IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE:	)	
	)	CA No. 01-12257-PBS
PHARMACEUTICAL INDUSTRY AVERAGE	)	CA No. 06-11337-PBS
WHOLESALE PRICE LITIGATION	)	Pages 1 - 133
	)	

MOTION HEARING - DAY ONE

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
January 26, 2010, 9:15 a.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
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P R O C E E D I N G S

THE CLERK: In Re: Pharmaceutical Industry Average Wholesale Price Litigation, Civil Actions 01-12257 and 06-11337, will now be heard before this Court. Will counsel please identify themselves for the record.

MR. HENDERSON: George Henderson, Assistant U.S. Attorney for the United States.

MR. FAUCI: Jeff Fauci, Assistant U.S. Attorney for the United States.

MS. ST. PETER-GRIFFITH: Ann St. Peter-Griffith, Assistant United States Attorney, Southern District of Florida, on behalf of the United States.

MS. OBEREMBT: Lori Oberembt, Civil Division.

MR. BREEN: Jim Breen. I represent the Relator, Ven-A-Care of the Florida Keys. And also, your Honor, in the courtroom today are three of Ven-A-Care's officers, its president, Mark Jones, past president, Luis Cobo, and Dr. Lockwood, which may be pertinent to the hearing later on today on the 12(b)(1) issues.

THE COURT: Why? I wasn't planning on holding an evidentiary hearing.

MR. BREEN: I understand, your Honor, but, I mean, they're here. We presented all of our evidence by affidavit and what have you, which I assume is acceptable, but on the outside chance that somebody has got a question or your Honor

has a question, they're available.

MS. THOMAS: Susan Schneider Thomas, Berger & Montague, also representing the Relator Ven-A-Care.

MR. LAVINE: Mark Lavine for the United States.

MS. BROOKER: Renee Brooker on behalf of the United States from the Civil Division in Washington.

MR. REALE: John Reale on behalf of the Boehringer companies.

MS. WITT: Good morning, your Honor. Helen Witt on behalf of the Boehringer defendants.

MR. GORTNER: Good morning, your Honor. Eric Gortner on behalf of the Boehringer defendants.

(Discussion off the record.)

MS. REID: Good morning, your Honor. Sarah Reid on behalf of the Dey defendants.

MR. MURPHY: Martin Murphy, also on behalf of the Dey defendants.

MR. KATZ: Good morning. Cliff Katz on behalf of the Dey defendants.

MS. LORENZO: Marisa Lorenzo on behalf of the Dey defendants.

MR. DALY: Good morning, Judge. Jim Daly on behalf of Abbott Laboratories.

MR. TORBORG: Good morning, your Honor. Dave Torborg, also on behalf of Abbott.

THE COURT: Have you set up an agenda for the first motion, or do I sort of pick out of a hat?

MR. REALE: Your Honor, the defendants conferred amongst themselves and have an order for presentation for our argument.

THE COURT: Did you confer with them?

MR. REALE: It is our motions that are left to be argued today, and so we let the government know what order of presentation the defendants had in mind.

THE COURT: All right, so what's the first one?

MR. REALE: Roxane's, your Honor, individual summary judgment motion, not the big BIPI motion that we discussed last week.

THE COURT: Okay.

MR. REALE: Your Honor, good morning.

THE COURT: Now, I'm really sorry. There are a few names I'm just sure of and others I'm less sure, and your name again is?

MR. REALE: John Reale, R-e-a-l-e.

THE COURT: Okay. And you're going to get a chart for me? Yes, so we're going to pass around a chart. I'm starting to know everyone's name but not as sure. Okay.

MR. REALE: Your Honor, today I'd like to talk about three arguments that Roxane raises in its individual summary judgment motion. The first is the time cutoff motion which --

THE COURT: Can we just really start with basics? I've tried to read everything. There are hundreds and hundreds of pages of briefing materials, so let me just start, what are the Roxane drugs?

MR. REALE: There are nine, your Honor. Let me see if I can get all these. It's Furosamide, diclofenac sodium, ipratropium bromide, Roxicodone, cromolyn, Roxanol, and hydromorphone. I believe that's all nine.

THE COURT: And the government tells me that the big-ticket one, the more expensive one, is ipratropium bromide. Is that right?

MR. REALE: That's correct, your Honor.

THE COURT: And one of the things I'll be looking to you all to do -- it's impossible for me to write opinions on every single motion in front of me, it's impossible. I would be here for two years. So what's really useful, I liked what the government did, which is said, okay, this is one big issue, for example, the NovaPlus labeling that if you resolve, maybe we can settle it. So if there are a couple of, like, key issues that will at least get us to the next stage, rather than wait for me to have to write on all this, it would be useful.

MR. REALE: Your Honor, I think that dovetails nicely with the arguments we're making with respect to the time cutoff because what we really are focused on and the information that was available to the government was on ipratropium bromide, the

government refers to as its big-ticket drug. And the other two arguments that I'll address briefly are a motion for summary judgment with respect to their unjust enrichment claim, and also to pick up on some of the arguments that we raise in our brief regarding the manner in which the government has calculated Medicaid damages. This argument is independent of the Daubert hearing you addressed last week, but it discusses some of those same issues; namely, extrapolation.

THE COURT: So the three issues again are?

MR. REALE: The time cutoff, the unjust enrichment claim, and Roxane's motion for summary judgment on the Medicaid claims, specifically to focus extrapolation.

Now, with respect to the time cutoff, the last time we met for summary judgment in October, your Honor referenced this notion that at some point if the federal law requires you to buy red rugs and I continue to sell you blue rugs, at some point the --

THE COURT: I said what?

MR. REALE: You made an analogy that at some point, if the law requires you to purchase red rugs and I continue to sell blue rugs, at some point the False Claims Act count fails. And that is precisely the Court's reasoning in the Massachusetts v. Mylan case. In that case, if you recall, your Honor, what you found is that the government knowledge defense was viable post-2002 because Massachusetts continued to use WAC

as a policy matter. And really the fact that was at issue in that case was, by all intents and purposes, a single OIG report which for the first time reported the degree of spreads between WAC and the acquisition cost of generic drugs. Despite that information, Massachusetts continued to reimburse using WAC, and the Court found that the government knowledge defense was viable from that point in time because it was a policy decision under the state.

And I'd also like to pick up a strand from the MDL in which this Court found that by 2001, there was a perfect storm of information that reflected the size of spreads to the marketplace and --

THE COURT: Well, while I did say that, they were branded physician-administered drugs.

MR. REALE: Correct.

THE COURT: So these are generic multi-source. It's a little different.

MR. REALE: It is, your Honor. You didn't have some of the same information that we see in this case with respect to ipratropium bromide.

THE COURT: Let me just ask you this about the time cutoff.

MR. REALE: Yes.

THE COURT: So I have ruled the government knowledge alone is not enough because sometimes they -- the statute

required them to do something even if they did something. I've said that I've disagreed with the government here that they have to actually have a formal written ruling -- what did you say, a "hall pass"?

MR. REALE: That's actually the word, yes.

THE COURT: Someone here pejoratively referred to it as not necessary. But you've now taken a legal position that I'm not sure I'm -- it's the gray area in between -- that mere acquiescence is enough to get you government knowledge defense, and I think the answer to that is "it depends."

MR. REALE: Your Honor, there's also an approval at work here too. We see that --

THE COURT: Well, sometimes there were approvals, but many times it wasn't. It was, "Yeah, we know about it, and we're bemoaning the fact."

MR. REALE: Well, they're moaning because they thought reimbursement was too much at certain points. But after the MMA in 2003, the government didn't abandon AWP. To this day --

THE COURT: So when do you think -- let me just say, the government knowledge defense I had thought you weren't moving for summary judgment on, but you were just saying that I shouldn't grant summary judgment in their favor.

MR. REALE: Your Honor, that part is true, but there's also a damages component. We think that the government can't recover damages post-2000. In addition, there are liability

issues, I agree, but there's also the notion that the government can't continue to recover damages once it understands all the particular --

THE COURT: Isn't that the same as the government knowledge defense? At some point it morphed into knowledge into sort of voluntary acquiescence or approval, whichever word we want to use. Isn't that part of what may be conflicted issues of fact on when it is and what it is?

MR. REALE: Well, your Honor, the information available to the government does relate to multiple claims of the False Claims Act. There's scienter, causation, and also the defendants' state of mind; but, really, what is undisputed here is the specific information that the federal government had available to it with respect to ipratropium bromide. Almost immediately when generic competition began at 1997, when there were principally only two manufacturers in the marketplace, Dey and Roxane, the OIG began to collect prices on ipratropium bromide; and within a year of generic competition in 1998, the OIG issued a report that documented mega-spreads for ipratropium bromide, and continued to collect prices on ipratropium bromide all the way up until 2001.

So while I agree that at issue in the MDL was a drug not at issue here, there was very specific and particularized information on ipratropium bromide available to the government, and our position --

THE COURT: When you say "government," it's confusing to me, so you need to be very specific. We've got to distinguish here between the federal government and the state governments.

MR. REALE: Yes, and I'm talking about the federal government in this case.

THE COURT: So you want to cut this off at the pass by saying the Center for Medicare and Medicaid Services approved of this mega-spread?

MR. REALE: They had information available to it, yes.

THE COURT: Well, no, just be careful here because the standard is a problem. Yes, they knew.

MR. REALE: Yes.

THE COURT: No, they didn't approve. So the issue is, where on the spectrum does acquiescence lie?

MR. REALE: Your Honor, I would argue that the government did know and continued to reimburse ipratropium bromide.

THE COURT: Yes, yes, yes, but is that enough for a government knowledge defense? I'm not sure as a policy matter, and that's the legal question that you're putting to me.

MR. REALE: Right, as a policy matter, the government continued to allow reimbursement for drugs like ipratropium bromide and generic drugs that incorporated the use of AWP. We see that in Medicare Part D.

THE COURT: Excuse me. But you're arguing that because Congress didn't change the law, the statute -- I think it was a statute, not a regulation, right? The median --

MR. REALE: Correct.

THE COURT: -- because Congress didn't -- you see how hard it is to pass a healthcare bill now. So you're saying, because Congress didn't affirmatively get up and change the statute, that as a policy matter, they were adopting the spread. That's your argument?

MR. REALE: Well, your Honor, when they wanted to set up a prescription drug benefit program, Medicare Part D, they incorporated AWP in there.

THE COURT: That's later. That may be true. I've ruled that. That's when Congress blessed it. But this isn't blessing it. They knew about it at some point.

So, anyway, I get the point. We should move on because I'm not spending all day here.

MR. REALE: Okay.

THE COURT: So you're saying, as a legal matter, I should cut it off in 2000 because they knew?

MR. REALE: Correct.

THE COURT: Because they knew, all right. What's the next argument?

MR. REALE: Well, very briefly, your Honor, with respect to unjust enrichment, our argument is simple: That

there's no evidence that the defendant, Roxane in this case, has ever been enriched. As part of the analysis for unjust enrichment, the government needs to show that there's something in our hands that should be in theirs. As we know, the reimbursement goes to the providers, not to Roxane. And there's no evidence of any indirect benefit in this case to support the unjust enrichment claim. They've had no expert testimony on damages, and they've asked the jury to speculate as to that causality.

THE COURT: Well, I've been curious about unjust enrichment. I've really ducked the issue because it's an alternative theory. Is it state law or federal law, unjust enrichment law, that I would look at in the --

MR. REALE: I believe federal common law, your Honor.

THE COURT: So everybody agrees it's the federal common law? Are there cases construing what the federal common law would be on this?

MR. REALE: The law on the unjust enrichment, as we've set it out in our brief, is not in dispute, your Honor. It's the evidence that we claim is missing from the government's brief.

THE COURT: It does vary sometimes from state to state, so are there federal cases -- I just haven't delved into it too much -- that say as a matter of federal common law that there's a meaning to it?

MR. REALE: Yes, your Honor.

THE COURT: Okay, so I'll look at that. That may be. It may be time for me not to duck that issue anymore.

But let me just ask you. It's always been an alternatively pled theory to the False Claims Act, so I've got so much to do, I haven't spent the time on it. Why do I need to now? Why do you say it's sort of a "it will settle this case" kind of legal question?

MR. REALE: Well, your Honor, our position is, it shouldn't be submitted to the jury if there's no evidence to support it.

THE COURT: Well, it wouldn't anyway. Isn't it an equitable theory?

MR. REALE: They've pled it as a separate claim, your Honor.

THE COURT: Well, sure, but isn't it an equitable claim, an alternative claim?

MR. REALE: Yes.

THE COURT: So I'm not sure I'd send it to a jury. All right, so, anyway, I'll think about whether I need to do that one. And what's the third one?

MR. REALE: The last point is Medicaid. Last week your Honor heard from the parties' experts, Abbott's expert and the government's expert, on the extrapolation; and as part of the Daubert inquiry, they focused on the reliability. Our

motion doesn't depend on whether or not Dr. Duggan's testimony is reliable or not. What we've asked, what we've argued is that the law requires the government first to establish the predicate of liability on a claim-by-claim basis. They have to look in particular on how a particular Medicaid claim was paid.

THE COURT: You mean for the millions and millions of claims involved here?

MR. REALE: Well, your Honor --

THE COURT: I'm not going to do that. That's ridiculous.

MR. REALE: For the state Medicaid claims data, there's actually a code -- well, let me focus then on --

THE COURT: No one's ever held that. Now, it may be true that there's not enough data. That was a very -- especially that chart that Mr. Daly gave me, the gray pool there where we don't know, but --

MR. REALE: Well, let's look at the state Medicaid claims data, and for that data --

THE COURT: Well, have you done it? I mean, they're allowed to extrapolate. You're allowed to undercut it by actually doing it.

MR. REALE: Well, your Honor, what we know is that in Massachusetts, this Court threw out all claims that were reimbursed on the basis of AWP because the Court found --

THE COURT: Sure.

MR. REALE: -- defendant's intent.

THE COURT: Yes, it was not reimbursed on --

MR. REALE: They've used those same claims to extrapolate. They've calculated damages on those claims and then extrapolated --

THE COURT: Right. Now, that's a different issue. So what you're claiming is, the extrapolation methodology is poor because it's relying on impermissible claims. Is that really what you're saying?

MR. REALE: Exactly, your Honor, and that's why I think payment basis matters. We also look at the California motion to dismiss ruling where the Court threw out all claims that were reimbursed on a MAC calculated by an actual acquisition cost.

THE COURT: Sure, so I think that's a really fair point, but that's a different issue than whether or not you're allowed to extrapolate. So you're saying I shouldn't be allowed to extrapolate when the payments were based on MAC, usual and customary, or some impermissible standard.

MR. REALE: Or federal upper limit as well, your Honor, because --

THE COURT: No, no, federal upper limit is different. That's a "lower than" methodology, and we'll be issuing an opinion soon on that. That's a different issue. But MAC, to my knowledge, U and C, and at least in some states that are

WAC-based, AWP, might be an impermissible basis for extrapolating. Is that what you're trying to say?

MR. REALE: Exactly, your Honor. I'd also like to highlight that the government's own expert threw out any claim in which the paid amount was higher than the bill charge, the usual and customary. Why? Because that shouldn't happen in --

THE COURT: Sure, that's fair, but then I just rule as a methodology, we should be winnowing out those claims.

MR. REALE: Exactly. That logic is just consistent with what I'm saying with respect to the Massachusetts holdings and with the California motion to dismiss ruling, that those claims should not be, one, you shouldn't calculate damages on them, and, two, the basis to then extrapolate to other states is faulty.

THE COURT: All right, so those are your -- so let me just -- I don't remember.

MR. REALE: Yes.

THE COURT: Did you move for summary judgment, or did you just oppose their motion for summary judgment?

MR. REALE: We moved, your Honor.

THE COURT: So you moved.

MR. REALE: We moved for summary judgment on all three of the arguments I just mentioned.

THE COURT: Yes, but those are just going to cut off some damages. None of them throw out the whole claim.

MR. REALE: Unjust enrichment and then --

THE COURT: No, no, excuse me. I said that improperly. None of them throw out the suit. You still end up at trial.

MR. REALE: That's right, your Honor.

THE COURT: And what do you end up at trial on?

MR. REALE: Well, your Honor, we would end up on trial for a portion of pre-2001 claims.

THE COURT: So I just want to understand because I'm trying to put together the trial now. So some of it is -- so what's left? Let's even assume you win everything, you win the whole kit and caboodle what you just argued, what's left?

MR. REALE: There is a portion of Medicare that would still remain in the case, and I believe --

THE COURT: From when to when?

MR. REALE: From 1996 to 2000.

THE COURT: All right, so that's left. And then why not Medicaid?

MR. REALE: And I believe there is a portion of some Medicaid claims left as well.

THE COURT: The same time period?

MR. REALE: No, your Honor.

THE COURT: Why? Why would it --

MR. REALE: For certain drugs, I believe it does relate back for some time period. For others, because of, I

believe, the statute of limitations --

THE COURT: So that's the relation-back argument.

MR. GORTNER: Exactly, your Honor. Ipratropium bromide would stay in both Medicaid and Medicare in '96 to 2001 if we get that end-of-2000 time cutoff. The other --

THE COURT: Okay, but that goes to your second point on the original source, all that stuff?

MR. GORTNER: Yes, and also this Court's ruling. The complaint only had ipratropium bromide. It wasn't till 2005 that these other eight drugs were added, so those only go back to 2001 -- I mean to 1999.

THE COURT: So ipratropium was what year?

MR. GORTNER: 1996.

THE COURT: And the others were?

MR. GORTNER: Beginning in 1999.

THE COURT: Okay, thank you.

MR. REALE: Your Honor, last, we also raised other arguments on our summary judgment brief, namely, the one that you've heard already, and that's NovaPlus.

THE COURT: Yes, NovaPlus is an important one to deal with.

MR. REALE: Yes, it is, your Honor.

MR. GORTNER: Right, we moved for summary judgment on that, and, as you recall, we argued it last time in October, but that certainly is a big issue in our case, your Honor.

THE COURT: These others may help. Unjust enrichment seems as if it won't help at all, and I'm not sure I'm going to rule on it. The time cutoff, it just seems like a variant of the government knowledge defense, and the Medicaid damages seems like a damages issue, so I'm just not totally understanding -- what this might do is help --

MR. REALE: It certainly will help in our discussions, but, your Honor, it also will streamline the case, given the volume of evidence we would have to present.

THE COURT: Maybe.

MR. REALE: If Medicaid damages continue to the present, that would knock off nine years of evidence that we would --

THE COURT: Well, that's a fair point. Medicaid to the present?

MR. REALE: Yes, in the complaint it's alleged to the present.

THE COURT: Medicaid, that's a really good point because I'd be worried about that. All right, so let me --

MR. REALE: Your Honor, if I may, I'd just like to hand up with respect to the particularized knowledge on ipratropium bromide, if it helps, just a time line and a basic background of what the facts are.

THE COURT: I'm not taking any more materials. I spent -- I'm sure you can understand -- I have spent at least

eight hours over the weekend reading, and some last week when I read the wrong stuff, and I am still not -- I'm only about 75 percent done. If you want to give me a chart, I'll take it, but I'm not taking that thick thing.

MR. REALE: Okay, your Honor, I will just hand you a chart then.

THE COURT: You all divvy it up. I can't -- I mean, ultimately I have to read it all.

MR. REALE: Understood. This chart is very straightforward. May I approach?

THE COURT: Thank you. A chart I'll take.

All right, the government, I think it makes the most sense, if that makes sense to you -- otherwise I'll get confused -- for you to oppose drug company by drug company, so we'll start with Roxane.

MR. HENDERSON: Yes, your Honor. With regard to the time cutoff, your Honor, I do think this is simply a government knowledge issue, plain and simple.

THE COURT: Let me just give you pushback on government knowledge. It's possible one could rule on a particular state that there wasn't enough to be government knowledge, or for CMS, that there wasn't enough to be a government knowledge defense as a matter of law; but a bunch of the state comments, some people were saying, "Yes, we knew, and we adopted it as a policy matter," and some 30(b)(6) witnesses

said, "No, we didn't at all." How am I going to resolve that without a trial on that? In other words, I see there being a trial on at least some states with respect to the government knowledge defense.

MR. HENDERSON: That could be, depending on your view of the law, of course, your Honor. Our position is that a trial on that particular issue is unwarranted because federal regulations, which govern state methodologies --

THE COURT: I'm likely to do a -- unless I were to totally eviscerate the government knowledge defense ever happening, some of the statements create a question of fact. They could be outlier statements; they could be taken out of context. But the way I was thinking about it, though, is, I've only got about eight states where those kind of comments were made or were quoted to me. So it's possible that with respect to any state where there was no such comment -- it's state by state, right, drug by drug, state by state? So it would be useful to at some point have your view on where there was states where there's no information at all about a government knowledge defense.

MR. HENDERSON: That certainly can be done.

THE COURT: CMS maybe we know enough about because that's one centralized decision-making point, and I can decide whether there's a fact question. But, for example, Illinois, was it, where your 30(b)(6) witness denied that there was a

policy, and there were some quotes that said, "Yes, of course we cross-subsidized at some point." I at least would have to, I think, hear people because maybe there was a government knowledge defense at one point and not at another point. You know, it's hard for me to see snippets of a deposition, but --

MR. HENDERSON: I think if your Honor rejects the legal position that I just set forth, then, yes, either a detailed state-by-state view of the existing evidence would have to be done, or we do it at trial.

THE COURT: Well, I can't do that.

MR. HENDERSON: Understood.

THE COURT: I'm essentially going to look at the briefs, and if there were conflicting statements, it's likely to be a fact question. And if there's no evidence from a state, then I think, they have the affirmative burden, they haven't met it. I mean, that's essentially how I'm going to go. And on CMS, I'll have to look and see if there's enough to be a fact question. I mean, that's realistically how I'm going to have to go.

But let me ask you this. There were some troubling things. I mean, at some point, any state that's still doing AWP after the Congress has rejected the standard has to be willing acquiescence.

MR. HENDERSON: Let me suggest why that's not a reasonable conclusion, your Honor.

THE COURT: That's what I've ruled before, right? I mean, in other words, we've now got standards nationally that AWP, everyone knows it's a bogus, faux, phony, fraudulent, use whatever word you want. I had an expert for the drug companies on the stand the other day. I don't know if anyone was sitting here. Mr. Daly was here, I think. He was laughing that anyone actually paid WAC, never mind AWP. He hooted. Now the issue is whether or not it's a WLP. So, I mean, I don't see how any state, once the federal government flat out rejected AWP as a standard, how any state can say that they aren't willingly acquiescing in it.

MR. HENDERSON: Two points, your Honor. I think, in considering that issue, your Honor should be mindful of the evidence that the defendants have never claimed in their setting of prices that they were aware of this government knowledge information or relied on it.

THE COURT: No, but, excuse me, that only is intellectually important if you use government knowledge to undercut scienter, okay. But at this point why wouldn't the defendants be correct in assuming that the whole world knows AWP is a fraudulent price? So it's like the Emperor's New Clothes. So if a state is continuing to use it, then they know about it.

MR. HENDERSON: And then, your Honor, that is ascribing to the states an intention to allow manufacturers to

control the treasuries of each state to shell out money to providers at whatever the manufacturer wants to specify.

THE COURT: Well, at some point they need to own their own thing, so at some point I'm going to cut off damages. Now, we're going to have to figure out when that is, and for purposes of settlement, which is where I'm going to push you all at the end of today, don't include them. You can pick up what the right stop is. Maybe it's the Medicare Modernization Act of 2003 or something like that.

MR. HENDERSON: But let me elaborate, if you wouldn't mind, your Honor, why we think damages after that is appropriate, and California is a good example, okay? In 2002 -- hang on. And actually --

THE COURT: A lot of states are still using AWP.

MR. HENDERSON: That's right, that's right.

THE COURT: How many?

MR. HENDERSON: A lot of states.

MR. REALE: The overwhelming majority.

MR. HENDERSON: The overwhelming majority of them is.

THE COURT: That's overwhelming to me.

MR. HENDERSON: And let me explain.

THE COURT: Why isn't CMS sending it out to them and saying, "We're not authorizing this program anymore"?

MR. HENDERSON: Give me a minute, your Honor, and I'll answer your questions.

THE COURT: All right, go ahead, yes.

MR. HENDERSON: In 2002 -- this is just an example of California, which is ahead of the game on this -- in 2002 they get a report from Myers & Stauffer showing big spreads all over the place. And at one end of the spectrum -- I'm talking about generic drugs -- one end of the spectrum, the spreads are pretty small. In fact, the majority of them are under 30 percent. But at the other end of the spectrum, we have the Abbott's, Dey's, and Roxane's, the worlds with spreads of 90 percent. And the middle is around 56 percent or something, okay. Now, of course, if they picked that middle, some drugs get way over-reimbursed, and other drugs get way under-reimbursed.

Well, after that, the state legislature in 2004, they instructed that reimbursement be based on actual sales prices, ASPs. They modeled it after the federal legislation, and they intended to compel manufacturers to report ASP information for all drugs, not just the Medicare drugs but for all drugs, okay?

Now, what happened after that in California? That effort was back-burnered because a couple of years later Congress, in the 2005 Deficit Reduction Act, attempted to fix the Medicaid problem by specifying that AMP data, average manufacturer price data, which is much more accurate, be made available to the states to use for reimbursement purposes. So California said, "Wait a second. Why should we go forward with

this ASP, which is going to impose more burdens on the industry, when we can use AMP data finally?" So in 2007 California changed its legislation to eliminate the ASP provisions and replace it with AMP so that reimbursement would be based on AMP data.

Well, later that year the Federal Court for the District of Columbia issued an injunction prohibiting CMS from distributing that information, the AMP information, and so California again was stymied. That legislation --

THE COURT: You know, is any of this in my record?

MR. REALE: No, your Honor.

MR. HENDERSON: Yes, bits and pieces of it, but of course --

THE COURT: You know, I can't --

MR. HENDERSON: Well, it's in. It's in our -- it's not in our briefs.

THE COURT: Well, you know what, I haven't been able to get through the briefs. I am not going to sit and cherry-pick through the record if it hasn't been briefed this way. But let me just say this: Highly unlikely that you're getting it to the present, okay? When you are trying to settle this, which I am going to send you all to do afterwards, highly unlikely, okay. But what I really want to understand is, do you need the unjust enrichment?

MR. HENDERSON: It's pretty insignificant potatoes,

your Honor. I think it's premature to decide it. You probably will never have to decide the issue, your Honor.

THE COURT: Because the False Claims Act is a --

MR. HENDERSON: It's a common law --

THE COURT: -- common law remedy.

MR. HENDERSON: That's right. And, as you said, it's equitable --

THE COURT: It won't go to the jury, right?

MR. HENDERSON: It's not going to go to the jury. Your Honor is likely to never see it, so I suggest your Honor just not rule on the issue. I don't think it's necessary.

THE COURT: And what about the damage issue with respect to the Medicaid that's based on MACs or U and Cs or -- I don't know that we got to that with Dr. Duggan. Did you winnow those out?

MR. HENDERSON: We'd have to -- your Honor, these arguments that Mr. Reale makes were not raised at all in the briefs.

THE COURT: These were not in the briefs?

MR. HENDERSON: They were not at all in the briefs.

MR. REALE: It is in our briefs in --

THE COURT: It is in your brief, the summary judgment brief?

MR. REALE: Yes, it is, your Honor.

MR. HENDERSON: Well, what they argue, your Honor, is

not that the extrapolation should have excluded the claims that were in Massachusetts. Rather what they --

THE COURT: If they were sent out across the country, they probably shouldn't include MACs and U and Cs and anything. Was there a way of -- I remember Dr. Duggan said he shouldn't include MACs either, so that's probably more of the damage analysis than the liability analysis.

MR. HENDERSON: That's correct. What Roxane has argued, and all of the defendants have really argued, is that any claim paid based on a U and C, MAC, or FUL should be excluded entirely, no damages can be calculated based on it. They're saying there's no causation for any claim in any state where payment was actually made based on the usual and customary, a FUL, or a MAC. They're basically saying, disregard the "lower of" formula. That's what they're saying, your Honor, not that Dr. Duggan's extrapolation methodology was in this particular regard inadequate.

THE COURT: But were there certain -- like, Ohio, as we know, had a unique formulation, as did New York which we've been looking at for FULs, they said pay at FUL.

MR. HENDERSON: Correct.

THE COURT: Have you looked to see whether there are other unique states that have those?

MR. HENDERSON: We have indeed, your Honor.

THE COURT: And have you excluded those states that do

that?

MR. HENDERSON: I think Alaska, for example, had a couple of years or less when they had a New York-type situation for FULs. And, quite honestly, that's such small potatoes, I don't know whether Dr. Duggan did that. But we have been very religious -- New York, for example, Dr. Duggan did not calculate any damages where a FUL was in place. And, likewise, as you said, in Ohio, Ohio had a MAC program that covered all generics, and they used the MAC regardless of whether the AWP-based number would have been lower, so it overrode the estimated acquisition cost component. All other states except for that little exception in Alaska, they don't do that. They follow the "lower of" methodology.

THE COURT: Okay.

MR. HENDERSON: So that's the point.

THE COURT: So you're saying, at the very least, the increment between what the MAC was and the AWP should be covered?

MR. HENDERSON: Exactly, exactly.

THE COURT: Okay, thank you. We should move on to the next --

MS. REID: Thank you, your Honor. Can you hear me all right?

THE COURT: Yes. Or, you know, we have that little -- if you wanted to come up. But you're fine.

MS. REID: On behalf of Dey, we are the second in the list of defendants for today's arguments on the motion for partial summary judgment. And just in response to your question of which drugs are at issue for Dey, albuterol sulfate from 1992 to 2003 for Medicare, 2008 for Medicaid. Cromolyn --

THE COURT: Wait a minute. 1992 to 2008?

MS. REID: Yes, on Medicaid. Cromolyn sulfate, also an inhalation drug, 1994 to 2003 on Medicare, 1994 to 2008 on Medicaid.

THE COURT: So 1994 to 2003 Medicare, and what's Medicaid?

MS. REID: To 2008, they computed damages through the first quarter of 2008. Actually, the complaint asks for damages to date, but the calculations are to that point.

Ipratropium bromide is from 1997 to 2003 on Medicare, and again to the first quarter of 2008 on Medicaid.

Your Honor, bearing in mind your effort to focus on things that present legal issues and only legal issues at this point in time, I would agree with your Honor based on the discussion today that my further discussion of time cuts is really not --

THE COURT: On?

MS. REID: -- time cuts and government knowledge is really going to raise more issues of fact. I respectfully disagree with what Mr. Henderson said in terms of which states

do or do not accept the "lower of" methodology.

THE COURT: Can I say, it does create questions of fact in some states perhaps, but the majority of states I received no quotes from anybody. In other words, there were some states where, you know, defendants did a nice job in saying, "Well, this person said X," and then the government came back and said, "But the 30(b)(6) said Y." But there were lots of states where I heard no disputes at all.

MS. REID: Your Honor, the common statement of facts submitted by the defendants in opposition to the government's motion for summary judgment laid out in long detail the disputes and the government knowledge state by state. And if it would be --

THE COURT: For every state?

MS. REID: For every state that I think we had, and that was most of them. And so, your Honor, if it would be helpful for us to just give you a list --

THE COURT: No. I'm not getting anything else. If it's in there --

MS. REID: It's in there.

THE COURT: -- we will look at it and see because --

MS. REID: Docket No. 6447.

THE COURT: You say every single state, there's some quote from someone saying, "We did this to subsidize pharmacy costs"?

MS. REID: I wouldn't say it's every single, but I would say it's an awful lot of them of the ones we took depositions.

THE COURT: We will look at those, and to the extent it creates a fact issue, it does; and to the extent that there's no state at all referenced, then you don't have it.

MS. REID: The other thing I would say, your Honor, is that the CMS evidence also, I think, bears review, in that we've laid out the numerous statements by CMS from the administrator level down indicating their understanding of AWP.

THE COURT: But, you see, this is -- and I feel like a broken record, to use an outdated term, but it does strike me that, yes, at some point they knew, and they were fighting really hard to change it. And you can't expect them to turn on a dime; it's the entire federal government. So knowledge isn't enough. It's got to be some either approval or voluntary acquiescence or some blessing -- I don't know how else to -- as a policy matter, so --

MS. REID: Your Honor, I understand the point, and I think where this leads is that this is a record best developed at trial where your Honor and the jury can see the witnesses and make the factual judgment as to where that gray area, where it falls: Is it as the government says, is it as we say, is it somewhere in between?

THE COURT: That may end up being the case.

MS. REID: If I may, I'd like to turn to something that I do think bears some focus. Dey and Dey alone moved for summary judgment to dismiss the joint scenarios for Roxane and Dey damages on Medicare, and I wanted to just really make it clear the chronology of that and what the briefing is on it because in retrospect it may seem somewhat odd.

At the time that we moved, we were in a situation where we had had two separate cases, Roxane and Dey. There was no allegation in our original complaint, or in the amended complaint that was filed three months before the end of discovery, of any collusion, conspiracy, or vicarious liability, or any mention of joint and several liability. Dey moved on a very narrow issue, and that issue simply was, and if you look at the very limited briefing on this point in the briefs, we said: Based on this complaint, and based on the fact that Dr. Duggan when we asked him why it was he had substituted Roxane and Dey's numbers and no one else, his response simply was "Because the government has sued each of them," we made the point that under the False Claims Act, that's not enough.

In opposition, the government's response was to say, "no," you can use concepts of general tort liability. They did not, however -- and they cited Parke-Davis on causation using tort notions and then a few common law tort cases. They didn't cite any False Claims Act cases that showed a case where two

separate cases had been in an essence joined for purposes of damages. And if you look at the few cases that we've been able to find where, you know -- and I apologize, your Honor, but this has all come up in a context that we really didn't have briefing on this until after --

THE COURT: And we're not having any more briefing either. I have a thousand pages of briefing. But let me just ask you this: What do you view is the -- proximate causation is the standard, right? I think in your brief even you use that.

MS. REID: Yes, but, your Honor --

THE COURT: All right, so it's proximate causation under the False Claims Act, right?

MS. REID: Your Honor, but this is what I want to point out and respectfully so. We finished this briefing. After the summary judgment briefing is done -- and the total factual evidence before your Honor on summary judgment on this is Dey's amended complaint, Dr. Duggan's testimony that he simply, you know, what he did, and then a couple of paragraphs from the statement of facts on how Medicare reimburses and what Dr. Duggan did. That's it. There's no other factual record on summary judgment. Summary judgment is closed. They moved to consolidate, and that is when we really get the --

THE COURT: We're not having any more briefing. So what do you want me to do right now? You can raise it at

trial.

MS. REID: We can raise it at trial, but what I want, I think, to emphasize to your Honor is the extraordinary, unprecedented nature of what your Honor is being asked to do, that we have been unable to find any False Claims Act case where any kind of joint liability, let alone joint and several liability, was applied in a case where the defendant hadn't sued the parties jointly. And you have it in cases of concerted action twice that we could find. Conspiracy, there's no allegation of conspiracy here; and, finally, the vicarious liability, and there's no allegation of vicarious liability here. So this is a matter of first impression for your Honor.

THE COURT: Let me just ask you this. First of all, you haven't waived it for trial. If you haven't briefed it, maybe you've waived it for summary judgment, but that doesn't estop you from waiving it at trial. But let me just, going even beyond that, you've also raised it, I think, as part of the damages calculation. So I'm not here to say you've waived the issue, regardless of whether I rule on it for summary judgment.

But let me just ask you this. Proximate causation we all agree is the standard. That's the standard under RICO. I think in your brief I found it. Everyone seems to believe proximate causation is the standard. So what does proximate causation mean? Typically, that you're a substantial factor in

causing the injury, and it's reasonably foreseeable as the law, Palsgraf, you know, as the law envisions it.

So I thought about it a lot since Dr. Duggan's testimony, where I think it was preserved. I'm not saying it was waived. Even if you're not in a conspiracy, and even if there's not a joint venture, which there's no allegation of -- in fact you were competing with each other -- that's the whole point of it, you were competing with each other -- why wouldn't you have been a substantial factor in causing the price, if that's the standard?

MS. REID: Well, your Honor, that I think -- first of all, the allegations are in the complaint that we're responsible for our individual acts, for our individual NDCs, and our individual customers. That's the first point I think to bear in mind. That's what they've alleged. It's a separate case. That's what they want to prove against us.

The thing that -- and your Honor is right. In terms of the reliability of the damage model, the fact of the matter is that on the array that Mr. Henderson has used so frequently, the Cigna array which your Honor may remember where, you know, Apotex comes into the market at an AWP a dollar higher than either Roxane's or Dey's, Alpharma is already in at a dollar higher, if you take the other persons, the other competitors in that array, exclude Roxane and Dey and leave them alone, just as Dr. Duggan did in reverse, you'll generate just the same

amount of damages. In essence, by picking and choosing, you can generate damages that are more than what Dr. Duggan says is the universe of Medicare reimbursement for ipratropium bromide. Dr. Duggan in his own analysis does not look at this from a point of joint and several liability. He divides it. This is not a case where it was foreseeable to Dey --

THE COURT: What if it isn't joint and several? What if it's simply, you're a substantial factor in causing it, they're a substantial factor in causing it, you're not in concert, but you both caused it? Maybe others did too, but they're not required to serve you, or maybe you could implead them.

MS. REID: The other point of it is, is what they've done is, at the point when generic competition is increasing, which is 2001 to 2003, that very point when, you know, your Honor has -- I know you hate this perfect storm, but, I mean, everybody knows what's going on. Generic competition is coming in like crazy in ipratropium. The market share for Dey is falling. And the government, two-thirds of its ipratropium damages are in 2002, 2003, and they're allocating all of those damages to Dey and Roxane.

THE COURT: They certainly knew for points of views of triggering a statute of limitations, and they certainly knew and it was public from the point of view of public disclosure, but that's different from whether they approved it. In other

words, knowledge comes in in different ways for different issues. And, you know, I feel like -- you've preserved the issue. I don't think knowledge is enough. It's got to be knowledge plus. Maybe not as they would argue a formal written rule saying "We bless it," but not just knowledge. So we've got a spectrum and a gray area, and I'll probably have to have a trial over it, or at least I may be able to rule on CMS as a matter of law. I think I may well be able to rule on CMS, at least for certain time periods, but not every single state because I don't know enough. Some states I can rule as a matter of law, some I might say is a fact question, and some I may say nothing. So if there's nothing there, you haven't met the government knowledge defense. But that's what the government knowledge defense is, right? You're just saying mere knowledge is enough.

MS. REID: No, your Honor. What I'm saying is a slightly different point, which is, this is a False Claims Act, automatic treble damages. The single damages on Medicare for Dey alone trebled are $600 million. What this joint scenario does, in the worst case for Dey, is to take a $750 million figure, treble it, and then add a half a million on the Medicaid damages. You're looking --

THE COURT: Wouldn't it be $600 million divided by two and then treble that?

MS. REID: No. I mean, what they're doing is taking a

$1.1 billion scenario in the worst case for Dey and trebling it, and saying Dey is responsible under their market share analysis for approximately $750 million of that trebled. And in a False Claims Act punitive statute, there is a fundamental, I think, problem, unfairness in doing that on a case that was brought individually, claiming for individual NDCs. They list Dey's drugs. They don't list Roxane's drugs. It was tried factually. You know, never was there a mention of Roxane.

THE COURT: What are you talking about now? Where was it tried?

MS. REID: What I'm talking about is the joint damage scenarios, your Honor.

THE COURT: You know what, when you say it was tried, where was it tried?

MS. REID: I'm sorry, I apologize. It was the discovery. I'm sorry, I apologize.

THE COURT: I thought maybe some other --

MS. REID: No, no. You were hoping maybe?

THE COURT: I was hoping. I start smiling.

(Laughter.)

MS. REID: I apologize.

THE COURT: Somebody else's opinion I can just sort of cite and say I agree.

MS. REID: I won't go further on that. I think I've made my point.

THE COURT: You have.

MS. REID: I think your Honor is completely right that the summary judgment issue is a limited issue of law. The whole issue of the liability and the methodology of these scenarios has not been tested. It is something that would have to be tested in some kind of a Daubert hearing probably.

THE COURT: I just already did that.

MS. REID: You did it for Abbott, your Honor.

THE COURT: I'm not doing another one. I mean, the thing is, if it hasn't been filed, it hasn't been filed. I can't -- I don't have -- didn't we have deadlines for filing these things?

MS. REID: The in limine deadline is April the 2nd under our pretrial order.

THE COURT: Oh, I see, so that's when you -- I see. I'm sorry, okay. So why did I do Abbott's, because --

MS. REID: They filed it in connection with their motion for summary judgment, but neither Roxane or Dey did because ours was really going to a causation point and not to the reliability methodology at this point.

THE COURT: I see, okay. Okay, thank you.

MS. REID: Now, if I could just --

THE COURT: You need to move it along because --

MS. REID: Okay, I have one other point, and, your Honor, if I can just hand it up, and I won't belabor the point.

This is actually something you read. This is from the Bradford declaration submitted on summary judgment. Dr. Bradford is our expert, and it simply illustrates why for Dey the payment bases that differ by state really do matter. If your Honor would allow my colleague --

THE COURT: If it's already in the record, that's fine. Did you share it with the government before? It looks like something from MoMA.

MS. REID: That's why I like it. Dr. Bradford --

(Laughter.)

THE COURT: It's actually very nice, I mean. . .

MS. REID: Dr. Bradford actually did analyze all the claims data. He analyzed it both for what he would call an error rate, which on the summary judgment record he found to be approximately 20 percent overcharge, he believes; and then he also analyzed the payment bases for the states. These are only the AWP states. He did it for the WAC states, and there's a figure, which I haven't given you, also attached to this declaration, which is Docket No. 6180.

What this shows is that in analyzing the claims data, anything that's red shows that he's unable to match it up to the formula or any other payment basis that was supposed to be used in that state. "MAC observed" is simply his assessment that MAC was being applied, even though it is not formally designated in a MAC column for the state. "Bill charges," the

black one, are the states --

THE COURT: Why are you giving this to me? This is going to be part of your Daubert motion?

MS. REID: Because I think, your Honor, it illustrates why the payment basis matters so much to Dey.

THE COURT: But this is a damage issue.

MS. REID: It's a damage issue, but it illustrates that it is not, as your Honor has discussed with Roxane, it's not a small issue, and it shows that the states did not apply their own formulas always.

THE COURT: But isn't that your argument at trial, let's say, for either why their damages are speculative or why they should be diminished? In other words, you might be right that, as a practical matter, states only applied MACs, even when there was a "lesser than" methodology, that as a practical matter, that's what they did. Then you reduce the damages for that state, right?

MS. REID: Yes. But I think it also goes to showing that the states are unique, that each one has different payment methodologies.

THE COURT: Yes, it might be, it might be.

MS. REID: And it also, I think, undercuts the government's assertion, which is not really supported by evidentiary cites, that a state would automatically have paid less than with the exception of one or two.

THE COURT: But I can't do that as a matter of law.

MS. REID: But I think -- okay, I understand.

THE COURT: That's maybe part of your motion in limine on damages or maybe what the argument to a jury is on damages, right? I mean, in other words, you might say, you know, 30 percent of these are paid on MAC, and they didn't do "lower than" when they could have; they were lower than, let's say, and therefore you should reduce the size of the damages by 30 percent, right? Isn't that the argument?

MS. REID: Right. I mean, yes, if your Honor is -- I think should continue your prior ruling as you did in California, that if it's a MAC methodology, it is not based --

THE COURT: But that's only if they paid based on MACs --

MS. REID: Right, and that --

THE COURT: -- and -- excuse me -- they didn't have a "lower than" methodology, or, as a practical matter, they didn't follow a "lower than" methodology.

MS. REID: Right.

THE COURT: Like, some states that's true. Like New York -- we've been doing the New York one -- they didn't have a "lower than." They only reimbursed based on FUL, so FUL became the key criterion. But if it's a "lower than" methodology, then why -- if the AWP would have been lower than, the fact that they had reimbursed based on MAC just sort of

limits the damages.

MS. REID: Yes. And your Honor, again, this may be a trial issue. I think there is a huge amount of evidence that the state would never have reimbursed based on these numbers. And in fact California, which, you know, Mr. Henderson just referred to, I mean, it is crystal clear that they would never have reimbursed based on those lower numbers, and indeed there's an injunction in place preventing them because of the access issue. So we're back to what we've argued before. I mean, this is not a simple matter.

THE COURT: So maybe you win in California. I'm just simply -- I can't do that in these motions.

MS. REID: I understand, your Honor. I would say, to the extent your Honor wants to look at --

THE COURT: If there's actually a court injunction in place banning any reimbursement at a certain figure, then for that period of time you win. You know, that doesn't mean you win for the whole period of time, but I have to do this state by state. So, anyway --

MS. REID: I would say that in our Docket No. 6297, in the statement of facts at around Paragraphs 227 to 235, particularly 235, does set forth the states where MACs are based on acquisition costs, proprietary Medicaid, agency formulas, and so forth. That docket that I have cited to you also includes the government's response, so you'll get the

complete picture, if you are so inclined to look at it.

THE COURT: Thank you. All right, I need -- do you want --

MS. REID: Thank you very much, your Honor.

THE COURT: Thank you very much.

MR. HENDERSON: Just very briefly, I guess all of this does remind me of our recommendation to the Court that the first trial go forward on Medicare only. It would certainly simplify a lot of things.

Just a couple of corrections. Ms. Reid --

THE COURT: All right, before we drop that, because that wasn't initially your position, if we go forward on Medicare, that's what we talked about last week --

MR. HENDERSON: That's right. Yes, that's the government's recommendation.

THE COURT: At this point?

MR. HENDERSON: Yes.

THE COURT: All drugs, all companies, Medicare?

MR. HENDERSON: Well, as a practical matter, that's only two drugs and Dey and Roxane. Dey and Roxane, ipratropium bromide, and then albuterol, which damages-wise it's a small drug, but there's some important evidence. Ms. Reid mentioned cromolyn. We have not calculated any Medicare damages for cromolyn, so it's not an issue.

THE COURT: Well, you're still pressing under

Medicaid, right?

MR. HENDERSON: Medicaid, yes.

THE COURT: So the only Medicare drugs are --

MR. HENDERSON: Ipratropium bromide, which is both companies, and albuterol, which is a Dey drug.

THE COURT: And what's Abbott?

MR. HENDERSON: Abbott has several Medicare drugs, vancomycin and its solutions, so there are a number. It's a bit more complicated. There are more drugs for Medicare.

MR. DALY: Judge, Abbott is here only for pretrial proceedings. We would be going back to the Southern District of Florida for trial.

MS. ST. PETER-GRIFFITH: Your Honor, the United States intends to move to have the trial heard up here.

THE COURT: Why would that make sense for me?

(Laughter.)

MS. ST. PETER-GRIFFITH: Because, frankly, your Honor, the only evidence that largely is different as between the three cases is the evidence from the individual defendant employees. The state depositions were all taken in conjunction with each other. A lot of the experts overlap, and obviously the federal witnesses were taken together as well. So, you know, your rulings pertaining to all of that evidence is going to overlap.

THE COURT: But can I just say, as a practical matter,

I don't know that I'm going to have time. I don't know that any jury -- you all told me it would take three months to try this case if I included everything, or at least, right? That was even just -- I don't know that I could get a jury to sit that long, and if I divide it all up, multiple companies, it might make sense to have a different court with more time.

MS. ST. PETER-GRIFFITH: We were not contemplating moving to have it heard with the Dey and Roxane trial, your Honor.

THE COURT: I'm just simply saying, I have Mylan and I have the Neurontin cases.

MS. ST. PETER-GRIFFITH: I understand.

THE COURT: So just it's a hard time crunch. And even if I tried these, then I'd still have had to do the Medicaid after them, right? I'm worried about that, so I don't know what I'm going to do on that. Who's the judge down there? Is there a judge been assigned?

MR. DALY: Judge Gold, your Honor.

MS. ST. PETER-GRIFFITH: He could, your Honor, but what we are concerned about is the risk of having to revisit a lot of issues that your Honor will have previously addressed.

THE COURT: Well, yes, I understand. I'll think about it.

MR. HENDERSON: Just a couple of brief points, and I don't want to beat the combined impact theory to death, your

Honor, but just a couple of responses to what Ms. Reid said. She said the factual information on summary judgment was just limited to the complaint. That's not true. The declaration of Carolyn Hilton, which was part of our motion to consolidate, was also part of our summary judgment papers, and that plainly sets forth the combined impact theory.

THE COURT: Let me put it this way: I don't know whether she has preserved it for purposes of summary judgment, but, as a practical matter, she can raise it at trial in a timely way, and she can raise it in a motion in limine in a damage thing, so at some point I am going to have to reach the issue.

MR. HENDERSON: Yes, I guess I'm not sure -- I was having a hard time interpreting Dey's position.

THE COURT: So regardless, maybe I won't address it here, but I've got to address it at some point, right?

MR. HENDERSON: Yes. Yes, jury instructions will be critical as to what the jury can consider in terms of how they determine proximate cause and how they calculate damages.

Ms. Reid complained that this is grossly unfair. We have to keep in mind that if we had sued all of the companies in the array, the damages figures would be very large. And, likewise, in the albuterol situation where we have Dey's, their evidence of creating a spread and marketing it is very substantial. And yet, because of the fact that there are a lot

of other companies in the arrays who we have not sued, the Medicare damages are very small, very small, less than half a million dollars. And, of course, if we had sued everybody and allocated a market share to Dey in that situation, the damages would be very substantial, Dey's share. So there's nothing unfair about looking at the proximate causes of the --

THE COURT: Well, fair or unfair, I've got to follow what the law is. Proximate cause means a substantial factor in causing X.

MR. HENDERSON: Yes.

THE COURT: And that it's reasonably foreseeable within the expectations of the law. And so I don't know whether fair or unfair. I suppose at some point, if the fine got high enough, it could violate the Constitution, but --

MR. HENDERSON: Correct. I agree with your comments.

One last comment. I think all of the defendants -- and my sister Ms. Reid also mentioned this -- rely in part on the Court's ruling in the California case where you dismissed claims that were based on a MAC payment. Our submissions on this include two affidavits, one by a California representative who explains the "lower of" methodology and provides actual support from -- actual data showing that if the AWP-based estimated acquisition costs were lower than the MAC, that is what the payment actually is made at. So it demonstrates the "lower of" --

THE COURT: Well, I think, didn't I throw it out on a motion to dismiss?

MR. HENDERSON: Yes.

THE COURT: And I think the other side hadn't really briefed it much.

MR. HENDERSON: That's correct.

THE COURT: And I think at the time no one really understood MAC or FUL, no one. I now understand FUL, but I'm not sure I understand MAC. And that may be state by state, right?

MR. HENDERSON: Well, yes, except that with very few exceptions, it's part of the "lower of" methodology, the MAC is.

THE COURT: That may be, but, as a practical matter, do they always just bill at MAC even if there were lower prices? I mean, I imagine that's what I'll hear about.

MR. HENDERSON: I don't think you will, except for Ohio, and I think there was a period of time where Hawaii --

THE COURT: Well, New York just paid a FUL and didn't have a "lower than" methodology.

MR. HENDERSON: Correct.

THE COURT: I mean, there may be some states that did, right?

MR. HENDERSON: But we've surveyed the state methodologies very carefully. The defendants have not raised

any issues with our summaries of the state methodologies.

THE COURT: That is true.

MR. HENDERSON: And so one can plow through all those methodology summaries and see exactly what the MAC program is about.

THE COURT: Okay, thank you.

MR. REALE: Your Honor, can I just have one sentence in regards to the approval issue? And that is, if you look at the papers and the docket entry that my colleague had highlighted for you, that what you will see is that CMS has approved from the state as part of their plan amendment request drug pricing information that shows spreads much greater than what they've sought as part of their EAC formula; and we would argue that that shows not only knowledge to CMS of what drug pricing information showed in that particular state, but they're approving rates that are much less than those studies would indicate.

THE COURT: Thank you. I was very impressed with the creative use of conjunctions. You managed to achieve that within one sentence.

(Laughter.)

MR. REALE: Thank you, your Honor. I keep my word.

THE COURT: All right.

Abbott, were you pressing anything now?

MR. TORBORG: Yes, your Honor. Again, this is David

Torborg on behalf of Abbott. The drugs at issue in the Abbott case are four: They are vancomycin, which is an I.V. antibiotic, dextrose, sodium chloride, and sterile water. The government is seeking recovery from 1991 through 2001. About two-thirds of their damages are Medicaid.

THE COURT: What were those years again?

MR. TORBORG: 1991 through 2001.

I wanted to follow up on two of Abbott's affirmative summary judgment arguments: one, our argument on the time cutoff, and, two, some additional points I wanted to raise on the basis-of-payment damages-type issues.

On the time cutoff, this Court made clear in its 2003 Franklin v. Parke-Davis case that the FCA does incorporate a proximate cause standard. And it is a well-established rule of proximate causation in common law fraud cases, RICO cases and every other fraud case that one might look at, that a party cannot recover for self-inflicted damages. If a party pays money when it knows of a fraud, it is the plaintiff's decision to continue with that transaction that is the legal cause of the injury.

THE COURT: Can I stop you there. But what if it's the statute that requires them to continue? In other words, it's not a business that can just say, you know, "You've got to be kidding, Buddy. Get out of here." But where the statute requires the use of AWP, the government doesn't have a choice.

MR. TORBORG: Yes, I actually wanted to make that point. I think there's a distinction we need to make here between Medicare and Medicaid on that point. Medicaid had the ability to take the information that the government gave them about our drugs during this time period --

THE COURT: Who did?

MR. TORBORG: Excuse me?

THE COURT: Medicare?

MR. TORBORG: Medicaid. Medicaid had the ability, when the government told the states about the spreads on our drugs in the middle of the claim period, to go out and set a MAC on those drugs. In fact some states did. And then there was the DOJ AWP effort. They could have done that if they wanted to. So for Medicaid we don't have the issue of, oh, they had to pay AWP, because that just wasn't the case for Medicaid.

So we cited a plethora of case law in our briefing to support the well-established notion that once the plaintiff knows of the fraud, it can only recover for a reasonable time after that, and I have a couple other cases I think the Court should look at.

THE COURT: So that's the post, once the Congress said in 2003 --

MR. TORBORG: No, this would be -- what we argue is, Ven-A-Care filed their complaint against Abbott in 1995. The

Bayer's article came out about a year later talking about our drugs, the specific spreads on our drugs. They lifted the seal and met with the states and told them all about it in the middle of the claim period. They also met with NAMFCU in 1998. I think one of your prior decisions talked about that. That's the drugs in our case.

THE COURT: The what?

MR. TORBORG: Your Mylan decision talked about a meeting with the National Association of Medicaid Fraud Control Units, with Ven-A-Care and what not.

THE COURT: All right, I just didn't catch the acronym.

MR. TORBORG: That's our drugs. They knew what was going on, and they had the ability to fix it.

THE COURT: Is that a mitigation, though?

MR. TORBORG: No, it's not because we are challenging a fundamental element that they have not proven their case, proximate causation.

THE COURT: But let's just say there was a fraud and there was a way to mitigate --

MR. TORBORG: Correct. Well, there's a way for them not --

THE COURT: Excuse me, excuse me. I'm not sure -- I mean, this is the gray area -- whether that rises to the level of approval.

MR. TORBORG: Well, this is where we see the case law drawing a distinction on government knowledge between liability and penalties on the one hand and damages on the other. In fact, there's a recent case that we cite in our brief, Butler v. Hughes Helicopter. It's actually not that recent. It's 1993.

THE COURT: I think I've cited that before.

MR. TORBORG: But that case actually says, even if relator's claims were live, actual damages, in contrast to civil penalties, could not have been found as a matter of law. So the case law does draw a distinction between damages recovery and penalties, and Abbott's motion does not seek to cut off penalties for conduct that occurred after the government was aware of the fraud. It's only damages. And it's based on the well-established notion that, as a matter of proximate causation, when the party knows of the fraud, they can no longer recover.

THE COURT: When there's something they can do?

MR. TORBORG: When there's something they can do here. And we cited a whole plethora of cases on this. The government didn't cite a single case rebutting that presumption, nor have they cited a single case --

THE COURT: Excuse me. There's no presumption. The basic --

MR. TORBORG: The basic rule of law. Nor has the

government -- what we really suspect, if the government had one, they would point this Court to a case where in a False Claims Act case they've been allowed to recover damages for six years after the allegations were made aware to the government. They haven't found a single case. There isn't one. What they're trying to do in this case is so novel, I mean, it's inconsistent with proximate causation law, and it shouldn't be allowed. It's not mitigation. Mitigation only comes once the elements have been established. We're saying --

THE COURT: You're talking the government knowledge case. That means the elements have been established, but you're trying to cut it short by the government knowledge defense, which I'm going to likely -- I think, at least with some of the states, may well be the case. I mean, I certainly think it was the case, it raises a fact question in some of the states, some of the states. But that's different. They have established liability, and then you say that the government knowledge defense -- that's what you're asserting on an affirmative defense, right?

MR. TORBORG: No. Well, we are asserting that, but the government can establish liability, like the statements were false.

THE COURT: Yes, they were clearly false.

MR. TORBORG: But to prove their case on damages, they have to show that these prices were the proximate cause of

damages.

THE COURT: They can prove causation.

MR. TORBORG: Proximate causation, and that's where the well-established principle of --

THE COURT: It was a substantial factor in causing the harm.

MR. TORBORG: That's the "but for" test.

THE COURT: What you're saying is -- and I'm not even sure what the government knowledge defense is, but at some point it either becomes so strong that it's an intervening cause, or, to the extent that you knew they were false, it undercuts scienter. I mean, I suppose you could argue in some circumstances that's the situation, where they, you know, affirmatively say, "This is okay because we understand it will subsidize the pharmacies," and you knew that, I suppose it undercuts scienter. But it's either an affirmative chopping off of causation, I suppose, or it's so extreme that it goes to scienter if you knew about it, "you knew/they knew" kind of thing. I don't understand why that undercuts liability. It's an affirmative defense.

MR. TORBORG: Well, because it goes to the well-established rule --

THE COURT: I guess it would conceptually --

MR. TORBORG: -- intervening cause.

THE COURT: It conceptually could go to either

scienter or causation.

MR. TORBORG: Yes.

THE COURT: I mean, I guess that's what you're saying, but that only gets you a fact question.

MR. TORBORG: Well, not if it's undisputed that they knew about the allegations.

THE COURT: I'm not going to go with mere knowledge. It's got to be more than that.

MR. TORBORG: Okay.

THE COURT: But if it's mere knowledge to the point they're so extensive that you knew/they knew and they didn't do anything, maybe. I don't know. Anyway, I get the point. You know, I feel like we're saying the same thing over and over again. Everyone's got the same point and it's a good one. It's the big overarching issue in this case, because it's clear there were false statements. It's clear that they caused, unless there's an intervening government knowledge defense, the payment of more money than should have been paid. Maybe we can debate how much more, but the basic lockstep is there, until it got to the point where they knew so much. And you've all said that, and it's a fair issue, and I will have to grapple with it. Okay? I don't want to hear about it anymore because, I mean, you've preserved it.

MR. TORBORG: On the basis-of-payment issues, I think the Court did understand in the California decision all the

issues that are in play here. It stated, for FUL claims, those claims were not going to be dismissed because there could be a possibility that you could draw a connection between the reported price and the FUL.

THE COURT: Right.

MR. TORBORG: For the MAC, the Court dismissed the claims where the MACs were not based on AWP.

THE COURT: Excuse me. That is true, but it was on a motion to dismiss, wasn't it?

MR. TORBORG: Yes.

THE COURT: Early, early on in the case where no one briefed it for me. I do not view that as binding law of the case. It was just that they didn't allege enough, and they never came back and alleged more. I don't even think I dismissed with prejudice, if I remember. I mean, no one explained it. No one knew it, I didn't understand it, I threw it out. I mean, that was not a summary judgment. It wasn't on a full record, right?

MR. TORBORG: It was based on a motion to dismiss.

THE COURT: Yes, yes, all right, I agree.

MR. TORBORG: The one point on MAC pricing that I think has been lost in the shuffle a little bit is that there has not been any evidence from the government that any MAC payment was an overpayment. There hasn't been any state who has come in and said, oh, that $9.60 that we paid for

vancomycin, instead of Dr. Duggan's $4.94, wasn't overpayment.

THE COURT: That's what this suit is about.

MR. TORBORG: This suit is about how our prices directly impacted the reimbursements, the AWP-based reimbursements. That's what this case is about. That's what the complaint says. It's not about the MAC payments.

THE COURT: But if on a "lower than" methodology they would have -- that's exactly what they're claiming, they would have paid lower than the MAC.

MR. TORBORG: Yes, but there hasn't been any proof, your Honor, that this difference between the MAC and Dr. Duggan's but-for price is usually not a very big number. It's actually an overpayment. It's a gaping hole in their proof.

THE COURT: I actually don't understand your position, but you've made it. All right, anything else you want to say here? It's the same issue. You've got a problem with government knowledge; I've got a problem with government knowledge.

Let me just ask again because I haven't talked to you for a long time about it: Do you view it as an affirmative defense or as undercutting the basic liability issues?

MR. HENDERSON: Certainly we view it as an affirmative defense.

THE COURT: Almost every court has recognized it, but

conceptually it's a little hard to figure out whether it's a -- I think in some circumstances it might undercut scienter, in some circumstances it might undercut causation, and in some it's just a defense.

MR. HENDERSON: I think in the way that Abbott has framed it as a causation issue is incorrect, your Honor. If it were a causation issue, it would be an absolute defense, and government knowledge has never been recognized as an absolute defense. Abbott's counsel quotes from the case in the Hughes -- let me just pull up my notes -- the Hughes case, and actually he's quoting, your Honor, from the District Court decision, not the Court of Appeals decision. The District Court had several alternative rationales, and one of which was, well, there wasn't any proximate cause because of the government knowledge. The Court of Appeals, however, your Honor, did not endorse that rationale, and the Court of Appeals simply affirmed the judgment on the ground that the Army in that case, the government, with the full knowledge of the defendant had approved the testing results, the conduct in that case, so it doesn't --

THE COURT: What do you do with his argument that once there was full knowledge, complete, total knowledge across the United States of America -- we can dispute the year, but everyone knew that there were thousand percent spreads -- that some states didn't adopt a MAC? Is that a mitigation issue?

Is it a government defense issue? What is it?

MR. HENDERSON: I don't think --

THE COURT: That's easy enough to do. Most states did it.

MR. HENDERSON: Yeah, I wouldn't know how to mitigate it, your Honor, without specific evidence that if they had reported accurate prices, this is what the state would have done. So in --

THE COURT: No, no. At some point everyone knew.

MR. HENDERSON: Yes.

THE COURT: At some point every state knew, and so why didn't they -- what do I do with the fact that most states adopted MACs and some didn't?

MR. HENDERSON: Because states, just like the federal government, take a long time to change their methodology.

THE COURT: At some point don't they have to bear the responsibility?

MR. HENDERSON: I submit not, your Honor, because they don't have to change their reimbursement system for some bad apples. They can --

THE COURT: At some point don't they have to take responsibility when, like, they're the outliers out there? Like, aren't there some states still paying flat AWP, not even minus a percentage?

MR. HENDERSON: No, no.

THE COURT: There's no one still like that?

MR. HENDERSON: Nobody like that. Clearly the situation is slowly getting out of hand, but, as I said, your Honor, there have been big efforts at the national level to try and fix this problem. And for any given state to completely --

THE COURT: CMS could just disallow a plan. I mean, at some level they -- I don't know where it is, but when you're settling this case, at some point the drug companies have to bear responsibility for this massive fraud, and at some point the states need to bear responsibility for not doing something about it once it's well known. And I think this trial, however I organize it, is going to have to deal in-depth with those issues. And when you try to settle it, I think both sides need to bear some responsibility here. Congress did it in 2003. It at that point became national policy that AWPs are phonies. And so at some point, once Congress stuck with it, they did it with full -- I think in certain narrow circumstances, right, they kept with the AWP? They did that knowing it.

MR. HENDERSON: That's true, your Honor. That was a Medicare statute. On the Medicaid side, they attempted it. It was blocked. Another attempt has been made, and as we know, it was in the House and Senate bills --

THE COURT: Actually I didn't know that.

MR. HENDERSON: -- to fix it. It was going to fix the problem.

THE COURT: I didn't read that whole bill, so --

(Laughter.)

MR. HENDERSON: Well, I know. And by the fact that this may not pass, your Honor, is that to be construed as Congressional acquiescence? Does that mean the state and federal governments approve of the conduct? I submit not. You can't infer that from a lack of legislation on a particular issue.

THE COURT: Why can't CMS under its existing authority disallow the plan and say, "Put in a MAC"?

MR. HENDERSON: And I'll tell you why, your Honor, and I'd like, if I may, to show you a graph. It's in the record.

THE COURT: It's in the record? That's fine.

MR. HENDERSON: It's in our record. This is the Myers & Stauffer graph.

THE COURT: They're the ones Dr. Duggan used, right?

MR. HENDERSON: And what this --

MR. REALE: Mr. Henderson, what page is that in your pack of material?

MR. DALY: L-23.

MR. HENDERSON: 23, thank you. And what this does, your Honor, is to --

THE COURT: Do you have an extra one of these or no? Maybe not. Well, it doesn't matter. I'll --

MR. HENDERSON: Okay, what this illustrates, your

Honor, is, what Myers & Stauffer did here was to survey about 669 products. These were products, they're generics, and they're not covered by a FUL. And they've expressed them in terms of an AWP minus a discount. They've expressed the actual acquisition costs as a function of AWP.

So if we look to the right-hand side of this chart, we see that about 23 percent of products -- that high bar goes up to about the 23 percent frequency -- of products, their actual acquisition cost is within about 20 percent below AWP, AWP minus 20 percent. So we can see there are a lot of products, generic products, that are prides pretty close to AWP. They don't have these huge inflations.

THE COURT: Within the speed bump?

MR. HENDERSON: Within the speed bump. And at the far left we see the ones who have inflated their prices, so that you'd have to go to AWP minus 95 percent to accurately reflect acquisition costs.

And you can see what happens if you just pick the middle point, okay? So if a state says, "We're just going to reimburse based on AWP minus 56 percent," you can see that some drugs get way under-reimbursed, the ones at the right-hand side, and other drugs get much too much reimbursement. And this makes absolutely no sense. It creates really perverse incentives. And I think this is one of the important reasons why states are really struggling to come up with a reimbursement

system to deal with these problems, because they don't have accurate pricing information. Yes, they can go out and do MACs, and we're seeing more and more states do that, but it is time-consuming and difficult.

THE COURT: Why?

MR. HENDERSON: Because in order to have up-to-date pricing, up-to-date reimbursement that doesn't get out of date --

THE COURT: I'm just saying, so many states have done it, it seems to be a best practice right now.

MR. HENDERSON: Yes, it's time-consuming --

THE COURT: Anyway, this is a nice chart. I understand the point. You're saying that as a matter of law, you can collect damages up to the present, even though everyone knows that these swings are there for these drugs.

MR. HENDERSON: Yes, where the --

THE COURT: All right, I get the point, and well argued, well teased up. What do I have left?

MR. DALY: Next would be the original source, pubic disclosure.

THE COURT: We're going to finish this morning, right?

MR. DALY: Yes.

THE COURT: Why don't we take a break.

MR. DALY: Yes.

THE COURT: All right, perfect. We'll take a break.

We'll do original source. You'll be out of here by lunch. And we can't do spoliation, right, because we have to wait till tomorrow morning?

MR. HENDERSON: Correct.

THE COURT: And then that's it?

MR. DALY: That's it, Judge.

THE COURT: Fabulous. Why did we think this was going to take two days?

MR. DALY: Well, I think the spoliation would have probably taken up the whole day --

THE COURT: I don't know anymore.

MR. DALY: -- but we had to kick spoliation to tomorrow. So I think you're right, Judge, we'll be done by lunch.

MR. BREEN: Your Honor, when you say original source, I assume you mean public disclosure?

THE COURT: Public disclosure/original source, what happens to the government if in fact some of these drugs you drop out of, do they get to relate back to it? So I think there are -- whoever the associate is or partner who dreamed up this issue deserves a gold star on his forehead, or her forehead, whether or not a person and an individual is an original source. It's the first time it's ever been raised to me. I don't think -- there's no case on it, right? Who thought of that?

MR. DALY: I'm not sure who on our team. It might have been one of my partners, your Honor.

THE COURT: A gold star, all right?

(A recess was taken, 10:43 a.m.)

(Resumed, 11:30 a.m.)

THE COURT: Okay? Let me start on a few things. I think we need to think about this company by company, drug by drug, complaint by complaint. So it's not helpful for a general discussion. When I was doing it over the weekend, I actually drew little charts for myself. So maybe if you could just take the first drug, what are the public disclosures, and then if it was publicly disclosed, why aren't they the original source for that drug? Doesn't that make -- did you have another way of organizing it, Mr. Daly?

MR. DALY: Judge, I was just going to talk about the public disclosures that relate to Abbott's drugs as a general proposition.

THE COURT: Yes.

MR. DALY: What I've handed you, Judge, is nothing more than exhibits that are already attached to our brief, but there's only seven of them, and I wanted to give you a more limited pile so it would be easy for you to find them.

THE COURT: That's fine. So let's start with, the first drug is what?

MR. DALY: Judge, the first drug I want to talk about

is vancomycin.

THE COURT: Vanco, all right. Which complaint does that show up in?

MR. DALY: I think it's in all of the complaints, your Honor.

THE COURT: I know, but I need dates.

MR. DALY: 1995.

THE COURT: 1995, so it was in the very first one?

MR. DALY: Yes.

THE COURT: All right, and what was the public disclosure that specifically referred to Abbott and vanco before then?

MR. DALY: Judge, if you'll turn to the first tab in the book that I've handed you, what that is is a 1992 OIG report which talks about vanco, talks about an investigation that was performed by the OIG into prices being charged in the marketplace for vanco. If you look at --

THE COURT: Page?

MR. DALY: Page 6, Judge.

THE COURT: And does it mention Abbott?

MR. DALY: I'll tell you, Judge, it does not mention Abbott by name. There are only four manufacturers of vancomycin, and so at this point in time, what this article is saying is that it's going out to get the EACs. It goes out and it gets the invoice prices from the pharmacies. And what it

finds in 1992, three years before the complaint is filed, is that the estimated acquisition cost, which in the paragraph above the box, they say they use the median invoice price obtained from the providers, and what it says is that you've got vancomycin EAC of $5, a median AWP of $19.17. So what you have is what amounts to a 287 percent spread, which is a mega-spread by the government's and I believe the Court's interpretation. So --

THE COURT: Okay, and then so -- all right, go ahead.

MR. DALY: So what I was going to say about this is, you know, we've all read your decision in Actavis, and, you know, I know that the Court is looking for both the name of the defendant and the drug, but the Court talked about some of the other cases where you have a limited group of potential defendants.

THE COURT: So this is, you're saying the argument is, there's only four, and so this put people on notice and --

MR. DALY: Well, certainly the government knows who they reimburse vanco for, and any provider would know as well, so, yes, our answer is that it puts the government on the trail of fraud. There's only four, and all you've got to do is look it up. So our position is, this is a mega-spread, this is 1992, and this is three years before Ven-A-Care filed its lawsuit.

THE COURT: Okay. And then why isn't -- is this the

only publication on vanco that precedes the 1995?

MR. DALY: Yes, your Honor, that specifically mentions vanco.

THE COURT: Okay. And why isn't the relator an original source?

MR. DALY: Your Honor, if the Court please, I would treat the original source separately as to all the drugs because the First Circuit's decision in Ondis from November makes it clear that it's not that they're the original source of the publication, but rather the --

THE COURT: Yes, I understand, but why is -- the relator says they filed the complaint, they told the government. So assuming this suffices, which maybe it does because it was such a small number of manufacturers --

MR. DALY: Right.

THE COURT: -- so didn't they get some information apart from the Blue Book and Red Book? GPO pricing, right?

MR. DALY: Pardon me?

THE COURT: Well, let me ask them that. So I'll go drug by drug.

So on vanco, why are you the original source if that's --

MS. THOMAS: Actually, your Honor, if we could, I'd like to address first why this is not a public disclosure.

THE COURT: Well, let me just say, I only want to hear

once from each, or we'll be here for the rest of our lives. So do you have a contention that they are not the original source, that this is a public disclosure?

MR. DALY: Yes, Judge.

THE COURT: Why?

MR. DALY: Because the evidence and the affidavits and everything that's been filed indicates that what the principals of Ven-A-Care did was, they simply took GPO price lists that were out there in the marketplace, looked at the compendia, and brought their sort of special expertise of being able to interpret this stuff to bear.

THE COURT: Let me just say, I may well agree with you that just simply being in the Red Book or the Medi-Span, First DataBank, is not enough to have some sort of unique, independent and direct knowledge; but the GPO stuff that they got in their hands from what the actual costs are is not publicly available in the sense of anybody in the world can get it. So why, if they had GPO information, why isn't that enough to be an original source?

MR. DALY: Judge, everybody had GPO information.

THE COURT: No, everybody did not.

MR. DALY: Everybody in the industry did.

THE COURT: I don't think that's the test. I mean, I could go out, just like I can get The New Yorker magazine or Barron's magazine, I can order it. You can go out and order

the Red Book, the Blue Book, or Medi-Span. But that's different. You've got to be a member of a GPO to get the GPO pricing, right?

MR. DALY: I think you do, Judge, I mean, but they had it because they were at the --

THE COURT: Well, why does that matter? It was direct and independent knowledge of what they could get from a wholesaler.

MR. DALY: Well, if that were true, but they also used the compendia to figure out what the AWPs were, and that is information that's out there in the marketplace.

THE COURT: All right, so fair enough. So one part is out there and one part isn't. Why isn't that enough to be an original source?

MR. DALY: Because I think what the cases suggest is that you have to be direct and independent; there has to be no intervening cause; there has to be -- you have to be the one who did it. And all they're doing is researching stuff that's out there and using the fact that they are -- they were a home infusion facility to put it together. And what Ondis says is that that kind of research, that kind of sort of putting it together and bringing your expertise to bear, does not make you an original source.

THE COURT: Thank you. What's your position on -- why isn't that a -- it's possibly a publication. I mean,

vancomycin, only four manufacturers. I mean, it does tell you. I mean --

MS. THOMAS: I think there are several reasons, your Honor, and it involves some understanding of this report. For one thing, it's talking about the payments for drugs in an ESRD, end-stage renal disease, program, which is Medicare, which means they're done under J-Codes. So it's not Abbott- or NDC-specific. The overall number that was set out in this report was that prices were 15 to 20 percent below AWP, which, as your Honor understands, Ven-A-Care has not alleged as a fraud.

THE COURT: He showed it to me where the estimated acquisition cost was $5 and the median AWP was $19. That seems like a much bigger spread than that.

MS. THOMAS: That was for one type of vancomycin which is exemplified in that chart. But, your Honor, what's important to understand is that both the EAC and the AWP that are set forth in this chart are median compilations of a number of different drug companies' products, so there's no way to ascertain from this whose product had the spreads. And if you'll notice the two columns all the way to the right, the number of facilities at or below EAC and the number of facilities that purchase above EAC, twelve purchased at or below, nine purchased above, and there's just a range of prices that cannot be attributed to Abbott. I don't believe this

report itself actually indicates that there are only four manufacturers.

And I want to note, your Honor, particularly, that Abbott's counsel has already taken your Honor on this trail of fraud, which is something that I think we need to really address. The notion of whether or not the government was put on the trail of fraud by a particular statutorily enumerated public disclosure we submit, your Honor, is simply the wrong analysis. The statute very clearly says that an action is barred if there has been a public disclosure of allegations or transactions upon which the complaint is based.

Government knowledge as a substantive standard was repealed in the 1986 amendments. What the government knew doesn't matter, and the First Circuit has recently reaffirmed that in the Rost opinion. There had been disclosures made from Pfizer to the government of the very fraud that was at issue, and yet a relator was allowed to bring the qui tam action because what the government knows, what the government actually knows is not a bar. So clearly using as a substantive standard --

THE COURT: Of course not, but what is publicly disclosed is. So I agree, government knowledge is not, so to the extent there were internal investigations -- what is publicly disclosed is. So the legal question is, when they publicly disclose a broad sweep between vanco and what is being

reimbursed, that is what is publicly disclosed. And the issue is whether because there are four manufacturers that's enough, or whether you actually have to designate Abbott. That's the issue, right?

MS. THOMAS: That is correct, your Honor, but in terms of assessing that issue, it cannot be with a view towards whether what was out there was enough to put the government on the trail of fraud, because if the government actually knows, it doesn't matter. So it's the wrong standard for evaluating.

THE COURT: Well, if they publicly disclose that vancomycin as an industry matter was grossly overpriced, that's a public disclosure, and you shouldn't be allowed to come in and be a relator on it unless you have original information. So, now, tell me about the original information.

MR. BREEN: Your Honor, I'll handle original source, if it's okay. Original source is obviously very factual-intensive.

THE COURT: They both are very fact-intensive, so -- but, in any event, original source, what did you have that was original -- not what was in Blue Book or Red Book -- what did you have that showed original knowledge of this fraud?

MR. BREEN: Your Honor, let's just go back to the beginning. And just to remind your Honor, we have filed and provided your Honor with a courtesy copy of two affidavits, one, Mr. Jones. It's a lengthy affidavit with exhibits that

are tagged so that you can click on the tabs, and it will pull up the correspondence or the --

THE COURT: Okay, I understand, but your briefs were impenetrable because what they didn't do -- I literally sat there this weekend -- it was a horrible weekend -- with a chart trying to chart this complaint, this drug, this original source. I want to know, specifically with respect to vanco, just help me with this, what did he disclose?

MR. BERMAN: But just to answer your question, your Honor, you're doing this chart. In the affidavit we provided your Honor, we did that. There is a chart that's got each drug, each complaint, and it's Exhibit 1 to Mr. Jones's affidavit.

THE COURT: Right, so now you tell me then, because reading the briefs, which is all I -- I didn't even physically have enough room in my car to drive it all home for the weekend.

MR. BREEN: I understand, your Honor.

THE COURT: So I didn't bring home all these affidavits. All I want to know is -- it would have been very useful in the briefs -- I think one of the defendants did it, an actual chart -- what is it that you provided that was original source to vanco?

MR. BERMAN: Your Honor, number one, what Ven-A-Care prepared as to vanco -- and it's very helpful to look at this

exhibit, look at what the defendants --

THE COURT: I don't have it here because I didn't bring down all the exhibits, so just tell me.

MR. BERMAN: Okay, counsel provided this to you. Defense counsel provided your Honor with a package of the exhibits he's referring to, and that's what I'm talking about.

THE COURT: Okay. All right, so where do you want me?

MR. BERMAN: Okay, I'm talking about Page 6 of the OIG report that defense counsel has brought to your Honor's attention.

THE COURT: But that's the public disclosure. I'm talking about original source.

MR. BERMAN: But I'm starting from this, okay, because you cannot evaluate original source, your Honor, without starting from the public disclosure, because the question becomes whether or not it's the same information.

THE COURT: What did you provide?

MR. BERMAN: Here's what Ven-A-Care provided: If you look at the purported public disclosure, you're going to see that nearly half of the providers are paying more than this middle point. It tells the government nothing about whether a drug manufacturer is intentionally manipulating its prices in order to create a financial inducement for the pharmacy or the clinic or the physician. There is absolutely nothing in this report that would give the government a plausible inference

that Abbott Laboratories, who without record support says there's only four manufacturers --

THE COURT: But what did you provide that shows that original source?

MR. BREEN: Now I'll go to that, your Honor, because they didn't have any of that from this report.

THE COURT: Please, you know, I don't want to be here all day. What did you provide?

MR. BREEN: What Ven-A-Care provided was the following: They were a customer of Abbott. They had Abbott GPO contracts that showed Abbott's actual prices to a point in the market, to a provider in the marketplace that was the smallest provider paying the highest prices. So they're on that side of the midpoint where these nine facilities would be if they were --

THE COURT: Say that again. So this is what the Jones affidavit does. So he provided GPO prices --

MR. BREEN: And he provided --

THE COURT: That Ven-A-Care paid?

MR. BREEN: Yes.

THE COURT: That Ven-A-Care paid and who else?

MR. BREEN: And any other small provider that would have been on the higher range of the prices generally and currently paid in the marketplace, which Ven-A-Care knows because they're there. The government by getting these

averages like this OIG report might have --

THE COURT: Okay, so you provided GPO information. That's all I want. I just want to understand what you gave that the government didn't already have.

MR. BREEN: GPO prices and prices actually paid by the providers paying the most for the product in the marketplace.

THE COURT: Why do you say it's the most for the product?

MR. BREEN: Because they're a small provider --

THE COURT: Yes, but GPOs aggregate, so they give you --

MR. BREEN: But there's different GPOs, your Honor.

THE COURT: Oh, so they had multiple GPO --

MR. BREEN: Multiple. Well, hospitals, for example, hospitals pay at this time -- we're back in 1992 now. ESRD facilities paid a fraction of the costs for everybody else.

THE COURT: Okay, all right. So now let me come back to you. He says he provides the GPO pricing --

MR. BREEN: And more.

THE COURT: Right, right, we have to move, okay.

MR. BREEN: -- and more. And Ven-A-Care, because they got into this whole false claims world, because of the kickback arrangements in Key West being funded by these inflated spreads, began providing the Inspector General at his request and his agents with actual pricing information beginning in

1993 to show the kickbacks being offered to them. And so they're going --

THE COURT: When you say actual pricing, you mean the GPO pricing?

MR. BREEN: The GPO pricing provided by Abbott's GPOs and other GPOs.

THE COURT: All right, all right, that's the same point, yes.

MR. BREEN: But it's more important than that, your Honor, because you've got a relator coming to the government and saying these price reports over time, not a point in time because any given day you could have a price report that's out of whack because the prices are coming down --

THE COURT: I understand that.

MR. BREEN: -- over time, we're showing you that Abbott is continuing to report these inflated prices. While their actual prices are going down, the spreads are getting bigger, and they're creating an inducement to us --

THE COURT: All right, all right, all right. You know --

MR. BREEN: That's what they provided the government.

THE COURT: That was a very succinct answer. You could have just said, "We provided the GPO knowledge over time that wasn't publicly available." Why isn't that enough to be an original source?

MR. DALY: Because I don't think it provides the full picture, Judge. In other words, that's only price at which it might be available in the marketplace. You've also got the AWP information from the compendia that all you have to do is get it and put it forward.

THE COURT: I agree if all they did was give them the Red Book, but they're not. They're giving them the GPO information which is insider to people in GPOs.

MR. DALY: But in terms of what they actually say in their affidavits, Judge, they just say that they took this information and researched. And what the court has said, the court's decision in Zverdup says that if you --

THE COURT: But that was an MIT guy who just went into a public record and reported on it. Wasn't that the railroad case?

MR. DALY: Yes.

THE COURT: That's different than if you yourself have insider information from your GPO and you report a fraud.

MR. DALY: What Mr. Breen I think is talking about is saying that they put themselves in the position to put all this information together and call it fraud. All we're saying about this OIG is, it's the X and the Y. It's got the true price, and it's got the allegedly inflated price. It doesn't have to have X, Y, and Z.

THE COURT: Excuse me. It may well be a public

disclosure. It's just that's only one, the first step in the analysis. Then the question is, were they an original source of information? And if they had GPO actual pricing information as to what wholesalers were charging, that may make them the original source that gets them to have relator standing.

MR. DALY: They may have had GPO pricing information along with every other GPO entity in the country.

THE COURT: Maybe.

MR. DALY: But they didn't --

THE COURT: But that's not a requirement that they --

MR. DALY: But the AWP stuff was public. It's in the compendia.

THE COURT: Okay, all right, I got the point.

All right, what's the next drug?

MR. DALY: In terms of the Z part of it, I would direct you --

THE COURT: No, no, the next drug, what's the next drug?

MR. DALY: The next drug are infusion drugs generally, Judge, and for that, I would direct you to two exhibits forward in the book I gave you. It's called Exhibit --

THE COURT: Infusion drugs are what?

MR. DALY: Dextrose, saline, and purified water.

THE COURT: Okay.

MR. DALY: Judge, this is a July, 1980 article in

Modern Healthcare. One of the things that the Ondis decision says is that it doesn't need to be a national or a wide-circulation publication. The Ondis case found that the Woonsocket Call was an adequate public publication. So this is an industry publication called Modern Healthcare.

THE COURT: But that's a difficult legal issue because it was so long before it was even a serious problem. I mean, so is something fifteen years earlier in a publication, especially before e-mails or Internet searches?

MR. DALY: Well, Judge, let me say two things about this article. What it's doing is talking about competition between Baxter and Abbott on group contracts, and on Page 2 what it says is that "If all 17,000 beds participate, the group will get about an 80 percent discount off current list prices for solutions and at least 50 percent off administration sets," and it gives the Abbott prices on the first page. So I'm not sure if I want to call it a serious problem or not, but in 1980, in an article that mentions Abbott by name, that mentions Abbott's drugs by name, gives the prices and says that in Kentucky they're giving an 80 percent discount, that is as serious as anything else in the case, Judge. So I would say, again, this is X and Y.

THE COURT: All right, so is that the public disclosure for these three drugs, the 1980 article?

MR. DALY: That plus other comments publicly by Bruce

Vladeck, the administrator of CMS, but these are the main ones for --

THE COURT: Excuse me. Who's Vladeck?

MR. DALY: He's the administrator of --

THE COURT: And when did he make these --

MR. DALY: I'm sorry, Judge. I think he made those in his deposition, so that doesn't count. So this is what I have --

THE COURT: So Modern Healthcare is what you have as the public disclosure. And the dextrose, saline, and purified water was added in what year?

MR. DALY: That's in '95 as well, Judge.

THE COURT: That's in 1995 as well?

Assuming for a minute that that's a public disclosure, what did you provide that was original? Did you provide GPO information on these?

MR. BREEN: Absolutely, Judge, and something much, much more than just GPO. When counsel says all we did was research GPOs, he's absolutely wrong. Ven-A-Care was in this marketplace. It was an infusion pharmacy. But I don't want to take time going into the facts.

THE COURT: Ven-A-Care was an infusion pharmacy?

MR. BREEN: Yes, ma'am, and community pharmacy. They had both licenses, a specialty pharmacy and a community retail pharmacy. They had both licenses.

THE COURT: So what did you provide to the government?

MR. BREEN: Here's what we provided to the government. Again, we've got to go to the public disclosure and show why it's not the same information or we provided additional information. The Modern Healthcare article is talking about the hospital market; and if we harken back to the '80s, hospitals were buying at a fraction of everybody else. There were all kinds of antitrust cases on this and everything else. They're talking about hospital beds, 17,000 beds. Ven-A-Care is a pharmacy. It doesn't have any beds. It's a small community or, in this case, specialty pharmacy for these drugs set up by two guys in Key West, a pharmacist and a nurse who treat AIDS patients. And they know that the prices being reported as generally and currently in the marketplace that they're in, not hospitals but they're in, the ones that Medicaid is paying for and Medicare is paying for -- Medicare pays hospitals on DRGs or cost plus, depending upon when we were. We're talking about pharmacies and clinics and doctors. So they're showing the government the real prices in the marketplace the government is reimbursing, not hospitals. It's GPO prices --

THE COURT: GPO prices.

MR. BREEN: -- Abbott GPO prices over time, showing that it's not a situation of, you know, it took a lot of catch-up on their price reports. In fact Abbott is reporting

higher prices every year when the prices are coming down. They're showing this to the government.

THE COURT: Okay, thank you. So is that it for Abbott?

MR. DALY: Judge, the other point I want to make with respect to Abbott is the difference between the '95 and '97 complaints which we address in our briefs. In the '95 complaint, there's no allegation of marketing the spread. There's simply an allegation that the spreads themselves induced people to buy then to take advantage of the spread, and that's all there is in Paragraph 44. That's in 1995.

In 1996, Barron's does the article that the Court mentioned, and in that article there is very detailed discussion of -- and that's also in the book I handed you, Judge -- but they have a very detailed discussion of marketing the spread. They talk about Abbott's NDCs, they talk about Abbott's spreads, and they specifically accuse Abbott and others of marketing the spread in that article. One year later in 1997, we have an amended complaint where Ven-A-Care adds marketing-the-spread allegations against Abbott, and we believe that that is based on the public disclosure a year prior.

THE COURT: Thank you. All right, so what's the next -- you're done, right?

MR. DALY: Judge, I do -- yes, except for one article I want to bring to the Court's attention, and it's the last one

in the -- strike that.

THE COURT: The Lexington Herald Leader? I mean, it can't just be that any publication at any time triggers the public disclosure. What about the Brookline Tab? I mean, at some point --

MR. DALY: Well, the Woonsocket Call is enough for the First Circuit. But this is a major newspaper in Kentucky, Judge.

THE COURT: Maybe it is for Rhode Island, but just it couldn't be -- there's got to be some limits on that, particularly in the pre-Internet world. How would somebody ever know about it? There's got to be some level of public dissemination.

MR. DALY: I think a major newspaper in the state of Kentucky qualifies as that. I mean, I don't think we can require that it be in the New York Times or the Boston Globe.

THE COURT: I don't know, but it can't just be any publication. There's got to be some level of publicness to it. Maybe it changes a little bit when you can sort of Google them, but it's a little harder to just get one publication. On the other hand, an OIG report qualifies.

All right, I don't want to spend any more time on it. No, I don't want to hear from you anymore (to Ms. Thomas). We've done it, right? We've done Abbott. Is there anything else to be said about Abbott?

MR. BREEN: Well, there's that what you mentioned before the break, your Honor, when counsel indicated there's no case saying that a relator original source can't be a corporation --

THE COURT: Can I just get through the drugs first, then we'll do the crosscutting issues?

MR. BREEN: Okay.

THE COURT: All right. You're for?

MR. KATZ: Cliff Katz representing Dey.

THE COURT: Okay.

MR. KATZ: The first complaint against Dey was in 1997, and before that complaint was filed, there were three reports discussing albuterol, and the '97 complaint is the first complaint to mention Dey's albuterol. The three reports were Medicare Payments For Nebulizer Drugs, A Comparison of Albuterol Sulfate Prices, and --

THE COURT: Do any of them actually mention Dey by name?

MR. KATZ: They don't mention Dey by name, but Dey was only one of a handful, one of about ten drug manufacturers at the time.

THE COURT: One out of ten that actually --

MR. KATZ: As listed in the Red Book. And if we take a look at, let's use the suppliers' report as an example --

THE COURT: Suppliers' report, is that a public

report?

MR. KATZ: This is an OIG report from June, 1996 called Suppliers' Acquisition Costs For Albuterol Sulfate. And on Page 7 of this OIG report that I'll put up on the screen, you can see that the OIG found that when albuterol was purchased directly from a drug manufacturer, it was purchased as low as 12 cents. Meanwhile, the reimbursement was around 40 cents, which is basically the same spread that's alleged by Ven-A-Care. They allege that the reimbursement was 40 cents and we purchased at 11 cents. And when you look at the working files for this OIG report, they say that the prices that were used to determine this were entirely based on Dey invoices. So this OIG report was based on Dey prices. So the government certainly knew that Dey was the maker of this albuterol and the spreads for Dey's albuterol.

THE COURT: When it says suppliers' costs, who are they referring to?

MR. KATZ: Those are entities providing albuterol to patients who are being dispensed.

THE COURT: Like pharmacies or like hospitals?

MR. KATZ: It could be either.

THE COURT: So they studied both classes of trade?

MR. KATZ: Yes, any entity providing drugs to Medicare beneficiaries.

THE COURT: And are there footnotes that refer to Dey?

MR. KATZ: Not in this report, but the government certainly knew that this was Dey's drug.

THE COURT: Well, don't forget, government knowledge isn't the test. It is what is published. But you would say that this was enough to be a public publication that would trigger the bar?

MR. KATZ: Right. And certainly you can look in the Red Book, and you'll see that Dey is only one of about ten drug manufacturers manufacturing albuterol at this time, so it's only a handful of drug manufacturers that you're really looking at.

THE COURT: Thank you. So is that the primary publication you're relying on?

MR. KATZ: Well, there's this report. There's two others which are very similar. There's also the same --

THE COURT: Did any of them specifically mention Dey?

MR. KATZ: No, not by name.

THE COURT: But they do mention albuterol?

MR. KATZ: Right, and it's the same spread that's alleged by Ven-A-Care.

THE COURT: Okay, thank you.

MR. KATZ: And there's one more public disclosure. That's the Barron's article, the Hooked on Drugs, that also mentions this report and albuterol. It doesn't mention Dey by name, but, once again, it's the same spreads.

THE COURT: The legal question is, where you have a disclosure in a publication by the government of an industrywide inflation of price, is that enough to be a public disclosure that bars them unless they're an original source, where they don't actually mention the manufacturer by name?

MR. KATZ: Well, we're only dealing with -- I mean, I believe that Dey is easily identifiable from this report, and that is the legal standard.

THE COURT: Well, it's not mentioned, right? So clearly if it was one of two manufacturers, yes. If it's one of a hundred, no. You know, one in ten, I don't know. I mean, that's the question, right? I don't know.

MR. KATZ: This report puts the government on the trail of fraud, including they were investigating Dey at this time. In fact, they started collecting prices regarding Dey as early as 1994, and from the working files we could see that they --

THE COURT: Excuse me, excuse me. That may well be true. That isn't what the -- it's got to be a public disclosure bar. So you're saying this is enough to be the public disclosure. It's not what the government knew. It was what was publicly disclosed. Okay, so thank you. Why --

MR. BREEN: Number one, your Honor, they weren't investigating Dey. This was an office evaluation report, not an investigation.

THE COURT: It was an investigation of albuterol.

MR. BREEN: It was a study, but --

THE COURT: So what? If it's a public disclosure -- it doesn't matter whether there's an investigation or a study -- if there's a public disclosure of a fraud that mentions a drug, so then the legal question is, is that enough if it doesn't name the manufacturer of a drug but there are only a few of them? There are cases on this.

MR. BREEN: I understand, Judge.

THE COURT: So but, now, assume for a minute it is. It easily goes away if you provided direct -- if you're an original source, so is there an easy answer to that?

MR. BREEN: Yes.

THE COURT: All right, so what's the answer?

MR. BREEN: The answer is, beginning in August of '95, long before this report -- I've got to go before it, I've got to go back -- August of 1995 Ven-A-Care was provided with an opportunity to engage in a healthcare venture down in the Keys, again, when the nebulizer drug market area, right when nebulizer drugs were becoming a hot item, okay?

THE COURT: Nebulizer is the spray?

MR. BREEN: Albuterol, albuterol. Well, no, that's the meter dose inhaler that comes in later.

THE COURT: Okay.

MR. BREEN: This is the nebulizer drug where there's a

piece of DME equipment, and there's all kinds of cases involving fraud in this area, DME equipment for people with chronic obstructive pulmonary disease, emphysema, children with terrible asthma.

THE COURT: Okay, so and what did you provide the government?

MR. BREEN: So once they were provided with that opportunity, within a couple of hours, Mr. Jones, who's here, contacted Mr. Lavine, who's here, an Assistant U.S. Attorney in the Southern District of Florida, and told them, "Hey, the problem we were having in the parenteral nutrition area and the stuff that Ven -- in the AWP area with the oncology drugs and Abbott's drugs, the infusion drugs, we're seeing it now in the nebulizer area."

THE COURT: What did they provide?

MR. BREEN: They provided the business information that was provided to them by a company called Pulmo Dose about how they could get into this venture, which is part of Mr. Jones's affidavit and is connected. Then --

THE COURT: What does Pulmo Dose provide, the GPO prices or wholesale prices?

MR. BREEN: Yes, they would begin to provide -- Pulmo Dose was another pharmacy, an intermediary pharmacy that was saying, "Hey, there's big spreads on these drugs. Let's get into business together," is basically what this first

entree was. So then Ven-A-Care begins to look at more closely its pricing because it provides inhalant drugs to its patients. It's got a lot of AIDS patients, and they use inhalant drugs also. They begin looking into pricing, and they begin to monitor Dey Laboratories' price reports and Schering-Plough Warrick's price reports.

THE COURT: What does that mean? You mean Blue Book and Red Book and Medi-Span? Those are publicly available. That doesn't help me.

MR. BREEN: That the government is using, and they compare them with the actual prices in the marketplace available to a small provider such as Ven-A-Care.

THE COURT: Through their GPO?

MR. BREEN: Through their GPOs and directly from Dey, from different --

THE COURT: They're providing actual cost information?

MR. BREEN: To the government.

THE COURT: So that's why they're an original source?

MR. BREEN: Yes. And they're providing it to the people that wrote this report.

THE COURT: Okay, why isn't that an original source? In other words, I could get into this very interesting legal issue whether ten was too many or whether ten was enough, but why do I even have to go there if they are providing original pricing information?

MR. KATZ: Well, what I think I'm hearing from Ven-A-Care is that they're implying that they came up with this idea to investigate inhalation drugs. The fact of the matter is that the government had already been looking into inhalation drugs, and we asked Ven-A-Care's 30(b)(6) witness about this, and they told us that Rob Vito, who was with the Office of Inspector General and looking into inhalation drugs, was already developing a report and contacted Ven-A-Care and asked them to provide the prices.

THE COURT: Fair enough, maybe that is true, but that isn't what the law is. The law just says they have to have independent and direct knowledge. It doesn't say the government can't already have started. I think it's a way of encouraging witnesses, actually, you know, people who know something about it even if it was publicly disclosed. That's why it's an exception to the rule.

MR. KATZ: I'm not sure how -- I don't think it's independent if --

THE COURT: Sure. I'm a company, I get pricing information, and I can buy it at a certain price, but the published price is something else. Why isn't that direct and independent knowledge?

MR. KATZ: Well, the allegation that there's a spread between the AWP and the actual acquisition cost was something that the OIG already had, and they told Ven-A-Care that there

was this spread, so --

THE COURT: Anyway, all right, I get it. So you're saying it's not good enough because the government already knew. I'm not sure that's enough of a --

MR. KATZ: And in terms of direct knowledge, it wasn't Ven-A-Care that was negotiating the prices with Dey, I mean, with respect to these GPO prices. There's no evidence that Ven-A-Care ever used these GPO prices to actually purchase the Dey drug, so there's no --

THE COURT: Why is that a prerequisite?

MR. KATZ: Well, they don't have any original source information of what the drug actually cost if you actually purchased it.

THE COURT: All right, I understand your legal position. Is there --

MR. KATZ: And if I can just make one more point. And Ven-A-Care doesn't have any original source information about reimbursement under Medicare or Medicaid because there's no evidence they ever submitted a claim for a Dey drug to either the Medicare or the Medicaid programs.

THE COURT: All right, thank you. Are there any other drugs for Dey?

MR. KATZ: We also have ipratropium.

THE COURT: Oh, the big one. Okay, so what's the publication? When is the first time they appear in a complaint?

MR. KATZ: Well, there's a November, 1998 OIG report called Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs, and on Page 7 of this report, which we'll bring up on the screen --

THE COURT: Excuse me. When was the complaint adding --

MR. KATZ: Oh, I'm sorry. Ven-A-Care first mentioned ipratropium as to Dey in 1999, and that was the third amended complaint in the Southern District of Florida.

THE COURT: 1999 is the complaint. So you're saying it's this 1998 report that puts them on notice?

MR. KATZ: Right, is the public disclosure.

THE COURT: Excuse me, is the public disclosure. You said it better. All right.

MR. KATZ: So if you look at Page 7, you'll see ipratropium bromide, and it says the median cost is $1.31 and the reimbursement is $3.34, and that's a spread of 155 percent.

THE COURT: This mentions Dey?

MR. KATZ: It doesn't mention Dey by name. And in Ven-A-Care's complaint in 1999, they allege a $1.70 cost versus a $3.34 Medicare reimbursement, which is a spread of only 96 percent. So certainly this report is a public disclosure of a large enough spread, of a mega-spread.

THE COURT: How many people manufacturer? Just two, right?

MR. KATZ: There was three manufacturers at this time.

THE COURT: Three?

MR. KATZ: In fact these prices for ipratropium bromide, according to the OIG working files, they look at Roxane's prices for ipratropium, Dey's prices for ipratropium, and Boehringer.

THE COURT: All right, so that was maybe in a public disclosure.

Okay, why isn't that a public disclosure?

MR. BREEN: Your Honor, it's absolutely not a public disclosure. If you look at the report, and what counsel didn't tell you, what they were comparing this with was what the VA pays for these drugs under the Federal Supply Schedule, which by law they get the lowest prices available to the largest commercial customers. So all they're saying there is, if we had some kind of price control and we told the manufacturer what they could charge the government for Medicare, then we could save money. And that's part of the problem here because everybody knows the government can save money if it uses its government purchasing power to force the drug companies to charge less to Medicare, but that's price control, and we don't have that in this country. That's a policy that our government --

THE COURT: So why isn't it fair to say it put them on notice that's what big pharmacies and hospitals get?

MR. BREEN: It puts them on notice of nothing as to -- okay, granted, it put them on notice as to what the best commercial customers in the country were making.

THE COURT: Right, Rite Aid or CVS or one of those.

MR. BREEN: And that's not what this false claims case is about.

THE COURT: It depends on how much into the peeling the onion: Do you have to just put them on notice of what the big guys get? Is that enough to put them on the trail? I mean, that's a legal question. Or do you have to put them on notice as to what the little guy is getting? I don't know. Assuming for a minute it's a publication -- I'm not assuming that -- assuming it is, what did you do that makes you an original source?

MR. BREEN: What Ven-A-Care did is, they began to provide the government with the albuterol and cromolyn prices in 1995.

THE COURT: Right, but "prices" is a protean term. What do you mean by the prices?

MR. BREEN: Actual market prices, confidential industry insider actual prices.

THE COURT: From your GPO?

MR. BREEN: Yes, ma'am, and other sources, generally and currently paid in the industry, not just GPOs; Ven-A-Care's wholesale sources, their specialty distributor sources, the

types of sources the industry insiders acquire their pharmaceutical products from. They began to do that as soon as --

THE COURT: This is all in the Jones affidavit?

MR. BREEN: It's all in the Jones affidavit.

THE COURT: All right, so why isn't that --

MR. BREEN: And there's more.

THE COURT: Yes?

MR. BREEN: Judge, they continued to provide -- they started examining ipratropium bromide because it was just coming off patent in 1996, and so they started watching their ipratropium bromide prices. And what happened as soon as I came off patent, which Roxane's parent held the patent, Boehringer Ingelheim, once it comes off patent, they start to see the spread grow and grow and grow. And they're in realtime reporting these prices to the Justice Department and the Inspector General. And there's deposition testimony attached to Ms. Schneider's affidavit -- U, V, and W happen to be the exhibits -- of Mr. Vito of the OIG and Mr. Tozzi of the OIG, and they tell you, as Roxane has told you, that Ven-A-Care provided the pricing and the spread information to the Inspector General so they could write these reports because they were doing this in realtime.

THE COURT: Thank you.

So is it the same argument as to why you don't think

that's original source? I mean, why isn't providing contemporaneous real pricing direct and --

MR. KATZ: Well, some of the same points I made on albuterol, but also I'd like to put up another exhibit, Exhibit 406.

THE COURT: That's just public disclosure, or is that on original source?

MR. KATZ: Both actually. What I'm going to put up are Dey's --

THE COURT: Where is this from?

MR. KATZ: This was Exhibit 406 to the summary judgment motion.

THE COURT: I missed it.

(Laughter.)

MR. KATZ: Now, what we can see here is, the top line is the AWP. The second line is the WAC. And you can see that there are a bunch of other lines, and you can see that the VA prices are virtually identical to plaintiffs' expert's so-called "true prices," their expert Simon Platt. So with respect to whether or not these VA prices are indicative of the marketplace, according to plaintiffs' expert, they are.

THE COURT: All right, fair enough, maybe it is. That's why I find the public disclosure stuff harder than the original source. Let's assume for a minute it is enough to put them on the trail, if that's the standard, especially when

there are only three manufacturers -- you know, it's not as hard as with ten -- but why aren't they, once they're providing realtime real pricing information, that isn't something that the government had?

MR. KATZ: Realtime pricing information was also publicly disclosed. As this chart shows, you have the WAC and the AWP. Both of those prices are publicly disclosed prices.

THE COURT: But those are phony prices. I mean, the issue is, who's going to provide the actual costs?

MR. KATZ: Well, we would disagree that those are phony prices, and if you compare --

THE COURT: Not true.

MR. KATZ: -- the WAC to the AWP --

THE COURT: So how do you get the actual acquisition costs.

MR. KATZ: Respectfully, your Honor, if you compare the WAC to the AWP, you come up with a spread of 120 percent. And Ven-A-Care only alleged for 1998, Ven-A-Care was only alleging a spread of 96 percent. So if you compare the AWPs and WACs for Dey's drugs, you can see the spread.

THE COURT: Okay, okay, so that's a different story. So it isn't the classic 20 to 25 percent spread that everyone in the industry thought about. It actually -- the WAC/AWP spread was significant enough, you would say, out of Blue Book to make that a public disclosure?

MR. KATZ: Right.

THE COURT: All right, well, that's interesting. All right, so what you're saying is that the WAC was -- how far below the WAC did the actual acquisition cost go? Is that --

MR. KATZ: As we can see, the actual acquisition cost tracked the WAC, and in some cases providers are paying more than the WAC.

THE COURT: That's interesting. So you're saying that actually the WAC here is far more representative of the actual acquisition cost, as opposed to some of these other drugs?

MR. KATZ: WAC was representative of the price to the wholesaler, from Dey to the wholesaler, and it is indicative of the actual acquisition cost.

THE COURT: The actual cost.

MR. KATZ: Yes.

THE COURT: So --

MR. BREEN: Respond to public disclosure first your Honor, Ms. Thomas will? Thanks.

MS. THOMAS: First of all, your Honor, it's really critical to focus on the fact that WACs and even AWPs in the Blue Book are not a statutorily enumerated public disclosure. Again, the question is not whether the information may have been out there in some format that somebody could obtain. It had to be a government investigation, audit report or hearing, or news media. First DataBank doesn't even describe itself as

the news media. It's a database service.

THE COURT: Do they say it has to be the news media?

MS. THOMAS: Yes, ma'am. The statute specifies it has to have been disclosed through news media, and we would submit, your Honor, that even Red Book is clearly not one of those statutorily enumerated sources which --

THE COURT: So there's no catchall for something that everybody in the world had?

MS. THOMAS: There is not, your Honor.

THE COURT: Not everybody in the world but everybody in --

MS. THOMAS: Right, not to mention the fact that not everybody in the world had it, but it absolutely is not.

THE COURT: Because absolutely everybody in the industry had those publications. So you're saying --

MS. THOMAS: It's still not a statutorily enumerated public disclosure. And the courts have been steadfast in saying that in order to disqualify a relator, the public disclosure has to have been pursuant to one of those enumerated means, and the courts just say that time and time again. So even Red Book --

THE COURT: Can I just stop you for a minute. Do you agree that that's part of the statute? I had missed that point, that it has to be under the statute. It can't be something everybody in the world has if it's not one of the

enumerated statutory categories.

MR. KATZ: I believe that Ven-A-Care is construing the statute too narrowly.

THE COURT: Well, do you have the exact language of the statute in front of you?

MR. BREEN: I've got it right here, Judge. I could put it up on the screen if you'd like.

THE COURT: Yes, I would like that.

MR. BREEN: If I could be toggled over.

MR. KATZ: If I can just make one point --

THE COURT: This will be useful, this will be useful.

MR. BREEN: And, by the way, your Honor, just to report to the Court, the Supreme Court has heard this issue, a related issue in the Graham County case, and we're waiting for an opinion on it.

THE COURT: Still? Oh, Really?

MS. THOMAS: Well, it's not specifically this issue. They're dealing with how narrowly the statute gets construed and whether the indications as to government reports and things apply to both state investigations and audits and reports as well as federal, but presumably the court will address in that context how strictly the statute gets construed.

It's also important to understand, your Honor, that WACs were frequently not published, even in the Red Book, putting aside the fact that the Red Book is not a statutorily

enumerated source for a public disclosure.

THE COURT: Well, that's interesting, that's interesting because unless somehow it picks it up through reference in one of these reports, it is not one of the statutorily -- even though the whole industry had it.

MS. THOMAS: That's just not the standard, your Honor, and that really harkens back to --

THE COURT: I know, you may be right, you may be right. Are there any cases that have looked at that?

MR. BREEN: Yes, and the reason I raise Graham County is because -- and both sides cite Graham County in their briefs -- that question has to do with whether state reports are a public disclosure, and whether when the Congress talked about administrative reports and hearings, it meant state also. So the Supreme Court -- and, you know, all we have now so far are the briefs and the oral argument, which is very interesting -- is trying to -- is interpreting -- but one thing is clear: Congress took away a limited amount of jurisdiction when it raised the public disclosure bar, but one thing is very clear: It did not intend to take -- it intended to be very narrow.

THE COURT: I see your statutory argument. Do you have any case on that? It does seem pretty narrow, what they're referring to.

MR. KATZ: There are cases that construe the statute

much more broadly, and we cite to those. I'll give you one example: United States ex rel Alcohol Foundation V. Kalmanovitz Charitable Foundation. In that case, the court considered scientific and technical journals as coming within the statute.

THE COURT: Because they considered those news media, is that it?

MR. KATZ: Right, and the court set a standard. I mean, if it's disseminated in a periodic manner and accessible, then --

THE COURT: Whether JAMA, the Journal of the American Medical Association. So that would be whether or not that fell within news media. It's a little harder with respect to these.

All right, I understand the legal issue. It's a very good legal issue. Okay, in any event, do you have any other points on that?

MS. THOMAS: Just with respect to that particular issue, your Honor, we've cited the Liotine case from the Southern District of Illinois which talks about a university Internet news publication that went to all its employees and stuff, and said that's just not sufficient to be news media. And I think it's important to focus on the way that First DataBank operates. It's basically a compendia publication --

THE COURT: You know what, I know First DataBank better than you do, okay? You know, I've had the McKesson/

First DataBank. I mean, First DataBank wished they never heard of me. So just I don't even want to -- I know what it is, and you've briefed it.

MS. THOMAS: Nobody reads it, your Honor. It's just loaded into a system. So conceptually --

THE COURT: People read it. Unfortunately, it's the publication in the field that's governed. Whether it's done a computer or done manually, I know First DataBank. So thank you, it's very helpful. Your statutory analysis was extremely helpful, and I appreciate that.

So what's the --

MS. THOMAS: There are just a couple of other points about public disclosure. I guess, quite frankly, Ven-A-Care is a little bit concerned if your Honor upon thinking about it decides that there is some hole in the original source and indeed decides to address public disclosure, which admittedly is normally addressed first, but --

THE COURT: No, excuse me. I'm discussing public disclosure first. That's why I started with public disclosure first. So assume for a minute that I find that Red Book is enough to be public disclosure or these general publications, let me ask you this: In what sense are you the original source? Did you provide GPO about ipratropium bromide?

MS. THOMAS: Yes, and, again, Mr. Breen's -- we split up this argument by public disclosure and original source.

Sorry to keep jumping up and down.

MR. BREEN: Sorry to do that, Judge, but, yes, there's additional original source information that goes to this point that Mr. Katz was making.

THE COURT: Which is?

MR. BREEN: You cannot devise a plausible inference of fraud in 19 -- whenever this was, 1998 or whatever, just because you're seeing this variance between WAC and AWP grow because that was -- unless you have more information, and Ven-A-Care had the more information. As your Honor knows from the McKesson case and from some of the other cases we've had here, the WAC/AWP range has not been static over time. It's changed, it's grown, and at some point perhaps improperly, which was what the McKesson/First DataBank case was about. But that has not been a static scenario. You can't just look at WAC/AWP and say, oh, it's beyond a certain point, somebody must be lying about something, because you don't know who's paying what within that range. You've got evidence provided by these defendants that some folks pay their list price, which is AWP. So you don't know who's paying what or how many. So --

THE COURT: So what did you provide?

MR. BREEN: So here's what we provided. Again, we've got the smallest provider that's directly in realtime a target of this information, in the ordinary course of business, taking that pricing information and showing the government that these

spreads are really growing. It's not that there's generally and currently available price --

THE COURT: Excuse me. You're saying the same thing. I just want to make sure. It's the same: You're providing GPO information in realtime over time.

MR. BREEN: Direct pricing and all the --

THE COURT: Direct pricing from what you're getting.

MR. BREEN: Wholesale --

THE COURT: All right.

MR. KATZ: And just to reiterate in terms of the spreads in realtime, all you need to do is compare Dey's AWP and Dey's WAC, and you see the same spreads that Ven-A-Care is alleging.

THE COURT: It does make it a little unusual in the sense that most WACs are much more -- it's formulaically tied to AWP. It's an unusual drug that way, I'd agree with you.

All right, so what's the next? We don't probably need to do ipratropium again, do we?

MR. GORTNER: All right, your Honor. Well, one quick thing on ipratropium for Roxane. Just to orient you to the big picture in terms of the complaints, we were the last ones brought in by Ven-A-Care. Our first complaint was in April, 2000, and it named only ipratropium bromide. And it was an unusual complaint because it not only named only ipratropium bromide, but it specifically only raised allegations about WAC

in Medicaid WAC states. The first AWP ipratropium bromide allegation and the first mention of the word "AWP" or Medicare is in February, 2002. So as we outlined in our brief, we believe the proper analysis of a public disclosure should be February, 2002, not April, 2000.

In any event, and then to follow up, the subsequent drugs did not come till February, 2005. So the two analysis points are February, 2002, for ipratropium bromide public disclosure, February, 2005, for the remaining drugs. And let's start just quickly with ipratropium bromide. Beyond what my colleague, Mr. Katz, mentioned of a 1998 VA OIG report showing spreads of 155 percent, there's also, if I may approach, a press release that was issued. This is one of a sequence of press releases by Representative Pete Stark, who your Honor is aware was the ranking Democratic member of the Subcommittee on Ways and Means Health, the committee that approved the Medicare budget every year, and he started issuing a series of press releases --

THE COURT: Did any of it make it into the press?

MR. GORTNER: Yes. That's the press release that I'm handing you right there.

THE COURT: No, no, no, I understand. Did any of them hit it into the general media?

MR. GORTNER: You know, we did not specifically find a general media, but as we cited in our brief, there's a

Footnote 7 of our brief on Page 11. "News media" is construed very broadly. That's what we were just talking about a moment ago. And press releases of this sort, there's case law that we cite in Footnote 7 that specifically says that press releases, particularly if it was a press release to the general public from Representative Pete Stark, counts as a public disclosure. And that press release --

THE COURT: Even if no media outlet ever picked it up?

MR. GORTNER: Exactly. I mean, that's the nature of the information that was available on its Internet website. It was available as a press release in 1999, and he followed up every year, both in 2000 and in 2001, he followed up and documented in this press release the actual spreads. And these aren't on VA prices, so we don't have that issue here. These are the purported spreads between wholesaler prices and what Medicare was paying for ipratropium bromide. And as you can see, in 1998 in that chart and in 1999, we have these spreads that are approximating what your Honor has referred to as so-called "mega-spreads," around 100 percent spreads, not terribly different from the 155 percent spreads that came out in 1998; but that shows, again, the VA may have had slightly better prices.

So in our papers, and I won't bring them in now, but we showed a similar statement in the Congressional Record following up in September of 2000 where again

Representative Pete Stark mentions ipratropium bromide spreads, specifically says AWP is a wholly artificial and grossly inflated price, specifically mentions --

THE COURT: A "stark" statement?

MR. GORTNER: Yes, exactly -- AWP pricing abuse, mentions financial abuse.

So this notion from these press releases, the statements from Representative Stark in the Congressional Record, as well as the OIG report, there's no doubt that ipratropium bromide was on the radar screen before February, 2002, even before April, 2000. And the issues of it being "financial abuse" or some impropriety were also in the public record. So with respect to ipratropium bromide, I think the issue about a public disclosure is front and center.

THE COURT: And just, again, what was in April, 2000?

MR. GORTNER: April, 2000, was the first Ven-A-Care complaint regarding ipratropium bromide. It did not raise any AWP or any Medicare allegations. Those were not added till February, 2002, and as is indicated --

THE COURT: So you weren't sued in 2000, or were you?

MR. GORTNER: Well, we were sued under seal in April, 2000, in this district.

THE COURT: About what?

MR. GORTNER: About WAC for ipratropium bromide and for Medicaid WAC states.

THE COURT: Oh, so the differentiation you're drawing is between WAC and AWP?

MR. GORTNER: And Medicare and Medicaid. I mean, I believe our analysis under Roffolo is, you can't just put a placeholder on some limited issue. And then after 2001, you have the Congressional hearings, the AWP issues are all over the place, and you can't add AWP and Medicare allegations in 2002, and total them back to a complaint that didn't have those claims in it in April of 2000.

THE COURT: Well, but if the WAC is fraudulent, then the AWP is fraudulent.

MR. GORTNER: Well, not necessarily. We didn't publish WACs. That's what's strange about the complaint. At the beginning of 1998, we didn't publish WACs for ipratropium bromide, so the WAC --

THE COURT: What did you publish?

MR. GORTNER: AWP.

THE COURT: Just the AWP?

MR. GORTNER: Just AWP. So it's an odd complaint, and I'm not in a position to explain the rationale. I believe that because there had been so much information on AWP in the 1990s and less information on the WAC issues, that April, 2000 complaint may have been an effort to pick out something that hadn't been publicly disclosed before, but the AWP issues did not show up until February of 2002.

THE COURT: So the legal question is whether or not I should view the 2000 or the 2002 as the placeholder on the issue?

MR. GORTNER: We certainly argue that it should be February, 2002, under either circumstance, the ipratropium bromide issue has been publicly disclosed.

Now, for the February, 2005 drugs, by then, setting aside the perfect storm of information, the Congressional hearings and everything else, Roxane happened to have been sued in ten states on all these different permutations of drugs. And these are public complaints. I cite the case law in our brief that a civil complaint that's not sealed is a public disclosure. That's black letter law. So there's no issue about public disclosure for those other drugs.

Now, in terms of whether Ven-A-Care has direct and independent knowledge, again, I think unfortunately we may again be in this gray area of law that we often run across in this particular case because we have case law that was cited. And I'll, frankly, concede it's not crystal clear because it's unusual to find a situation where you have what Ven-A-Care provided here to the government on Roxane, which is essentially McKesson's working database. Every McKesson member has a working database, which it itself has a screen that calculates spread by itself. It has an AWP inputted from the FDB or Medi-Span. It has its own wholesaler contract prices, and it

automates it and does the spread. That's the net total information that Ven-A-Care provided the government on Ven-A-Care. You see a couple invoices that they bought in 2000 from a GPO. So this is information. On the one hand, it may not be available to everyone on the planet, but it's available to everyone in the industry. It's not the prototypical information you have where you have a whistleblower --

THE COURT: Well, they say they're getting information only because they're a member of a GPO.

MR. GORTNER: And, again, we submit to you in the brief that that is closer to the type of prohibition on direct and independent knowledge that involves gathering information directly and entirely from a third-party agency, even if that information --

THE COURT: Don't you always get price from someone else if you're the buyer?

MR. GORTNER: Well, to some extent, but the classic thing here, and particularly the marketing-the-spread allegation, which I'll get to in a moment, is that you're inside the company. I mean, that really is the structure of the original source. I mean, you have some information because you worked in the pharmaceutical industry, had involvement with Roxane sales representatives, worked at Roxane, had some true direct and independent information of this pricing scheme. That is the concept here, as opposed to receiving automated

information from the largest wholesaler in the country that thousands and thousands and thousands of other pharmacies have access to, and just simply passing that working database to a party. We submit that that's a lot closer to relying only on an intervening agency. And, as your Honor is well familiar with, there's that body of case law on what happens when a relator really excessively relies on an intervening agency or other information that wasn't their own information.

Now, with particularity, on the marketing-the-spread allegations, when you look at the government's complaint, which is the latest amended complaint, there are pinpoint marketing-the-spread allegations in there, things like Roxane set and manipulated its AWPs, Roxane trains its sales force on AWP marketing. It's undisputed in the record and the testimony we cited in our brief that Ven-A-Care had no contact whatsoever with anyone from Roxane. Roxane, no sales representative ever contacted Roxane, ever tried to sell a drug to them. Ven-A-Care knew nothing about how we set our prices, how we marketed our drugs. So on that entire bandwidth of claims, those are constructions that come directly out of discovery that Ven-A-Care had done in other cases. But that's also impermissible under the original source doctrine. You can't do discovery --

THE COURT: Right, that would be, that would be.

So what's the response from the two of you?

MS. THOMAS: Okay, just a few quick points, your Honor. First of all, it's really critical to pay attention to the fact that the First Circuit in Woonsocket just recently, very recently, stated the applicable standard: "Public disclosure occurs when the essential elements exposing the particular transaction as fraudulent find their way into the public domain." And lest your Honor is concerned that this "public domain" means you don't have to interpret the statute carefully, the court then goes on very specifically to say that it has to have entered the public domain through one of these statutorily enumerated sources. But the standard that it sets out is that the public disclosure occurs when the essential elements exposing the particular transaction as fraudulent find their way, through statutorily enumerated sources, as public disclosures.

The press release that Roxane talks about, first of all, it's actually very interesting that this press release, to the extent that it's talking about any possible wrongdoing or benefit being gained, it's only talking about the providers. Congressman Stark, for whatever reasons that he chose -- and I think Mr. Breen may address this a little bit -- talks about the fact that use of the drug has soared as the providers' profit margin has soared. So to the extent that there is any indication that perhaps something is dirty in this area, the focus was not on the manufacturers through this press release.

It's also critical, your Honor, as your Honor picked up, that there is no showing that this press release was ever picked up and run by any news media. And it's not as though people didn't look. Your Honor can rest assured, I am certain, that defendants looked as hard as humanly possible to find someplace where this press release actually hit the news media.

THE COURT: Well, it eventually made its way into the Congressional Record, so that would be enough, right?

MS. THOMAS: I'm sorry?

THE COURT: The Congressional Record should be enough.

MS. THOMAS: I don't recall if this was.

THE COURT: Well, something was, a 9/2000 something --

MS. THOMAS: I don't recall that. Perhaps --

THE COURT: A 9/2000 something from Congressman Stark hit the Congressional Record.

MS. THOMAS: Well, he made various comments in connection with hearings. I don't recall that there's any indication that these press releases hit the Congressional Record. I'll look into that, but I don't think that's correct.

THE COURT: And you would agree that anything gleaned from complaints in other actions or discovery in other actions isn't good enough?

MS. THOMAS: Pardon me?

THE COURT: Anything gleaned from discovery in other actions is not an original source?

MS. THOMAS: We will get to that in a minute. I don't think they were actually talking about discovery. They were talking about the complaints --

THE COURT: Both, both.

MS. THOMAS: -- which we will address.

THE COURT: Both.

MS. THOMAS: But it's important, first of all, with respect to what was alleged in the original complaint in 2000, it is very clear, your Honor, that that complaint does refer also to Medicare. It makes reference to AWPs. Specifically in Paragraph 28 it talks about spreads. In Paragraph 56, there is references to wholesale prices, which obviously include AWPs. So we do not accept the distinction that Roxane tries to draw that the 2000 complaint was of such a limited nature.

THE COURT: Right, so then we go back to whether that VA report is enough.

MS. THOMAS: So, correct. I mean, that just sets the bound as to when you have to look to see whether there was public disclosure. And, similarly, the notion that the government is only alleging counts based on marketing the spread, because they happen to include examples of that in their complaint, is not true. That is not a requisite element. The government very definitely alleges just false price reporting. So whether or not Ven-A-Care had specific information of marketing the spread by Roxane is really

irrelevant, your Honor.

THE COURT: Okay, so now let me just hear Mr. Breen talk about, why were you an original source on this?

MR. BREEN: First off, your Honor, lest I forget, our original complaint against Roxane filed in April of 2000 specifically describes AWPs and how they were manipulated and what have you. Granted, we modified our allegations in the amended complaints, but we mentioned the AWPs before that. But specifically in terms of original source, let's remember that these GPO prices --

THE COURT: Just tell me what you did.

MR. BREEN: Yes, your Honor.

THE COURT: You reported the GPO --

MR. BREEN: Ven-A-Care's GPO prices. They're the prices negotiated by the GPO for Ven-A-Care.

THE COURT: Well, it's not just for Ven-A-Care.

MR. BREEN: No, for its members, but Ven-A-Care is one of them, so it's not just the GPO prices.

Now the press release, which is, I think, the main new thing that Roxane has raised in addition to the stuff we've already addressed. The Stark press release, I'm going to address that now.

THE COURT: Didn't she just do that?

MR. BREEN: Well, she did from a public disclosure perspective, but I'd like to address it from an original source

perspective.

THE COURT: Okay.

MR. BREEN: If I could just plug this in real quick --

MS. THOMAS: In case for some reason you don't buy my argument, your Honor, he's going to mention that we were indeed the original source.

MR. BREEN: Your Honor, this is a page, just a page from the Exhibit 2 to the Jones affidavit, and it goes on for hundreds of entries where your Honor can just click on each of these disclosures Ven-A-Care made to the government. This one which I'm going to click on in a moment was Ven-A-Care's disclosure of this ipratropium bromide issue to Pete Stark, who had asked for Ven-A-Care's help as a source since 1992, and you'll see tons of Pete Stark communications in here going back to 1992 where Ven-A-Care reported this to him.

THE COURT: What did you report?

MR. BREEN: I'm going to show you that right now.

THE COURT: Okay.

MR. BREEN: Tab 101, your Honor is -- I just lost it.

(Discussion off the record.)

MR. BREEN: Tab 101, these are all the Ven-A-Care disclosures to the government, your Honor. Now, this is Ven-A-Care providing to Bill Vaughn, Congressman Stark's office, information it had just given to the OIG. And -- one second, Judge.

(Pause.)

MR. BREEN: To Bill Vaughn in Mr. Stark's office. He's Stark's chief of staff at the time.

I'm apparently having an issue. Here it is, here it is, Judge. I'm sorry.

THE COURT: I tell you what, I have to be somewhere at lunch at 1:10. Now, you all could come back afterwards if you wanted to, but I thought I'd give you the afternoon off, so --

MR. BREEN: I apologize. I put it up now. Just I was having computer issues.

THE COURT: No, I don't blame you.

MR. BREEN: It's the same material that Congressman Stark used in his press release, and the next tab, the next tab --

THE COURT: What's original with you in that list?

MR. BREEN: The spread, Ven-A-Care's cost per unit right here. This is what Congressman Stark was using. And then the next stab, which I won't go to because it will probably blow the computer up, here's Ven-A-Care's actual information they provided, provided to the Congressman. And the next tab is Mr. Vaughn sending Ven-A-Care a copy of the proposed release that Congressman Stark is going to provide.

THE COURT: Okay.

MR. BREEN: So my point is, Ven-A-Care is not just a source, it's not just an original source. It has been the

source of actual pricing information for prices generally and currently paid in the marketplace, which is the standard for Medicaid, and the reasonable prices paid by prudent purchasers for Medicare, for Congress, for the OIG, for the GAO, for the Justice Department since 1992. It has been the one industry insider that has been willing to make its actual pricing information available on an ongoing basis and to show the government how these spreads grow for companies that are misrepresenting, how they don't grow for companies that aren't. And that's 80 percent of the dollars, by the way, Judge, to this day are spent on drugs where we don't have the spread issue.

THE COURT: All right, thank you. I think I've got an understanding of this issue now.

So there was one legal issue, which is, if I knocked out any one of the drugs, you would argue that the government's complaint would not relate back because there would be no subject matter jurisdiction. That's a very interesting legal argument where there's not a lot of case law on it. Isn't that the --

MR. BREEN: There's also the corporation and relator, your Honor, and there is a case right on point, two cases. The Minnesota Nurses case which we cite in our brief -- and I've got the quote, I could put it up, but we're in a hurry --

THE COURT: I read that, yes.

MR. BREEN: -- specifically says that Congress intended for organizations to be relators, and a corporation or organization can be an original source. They take that individual --

THE COURT: Not since Citizens United two days ago. I'm thinking that individuals and persons are different things, so -- someone made that comment, right? So --

MR. BREEN: And, your Honor, the First Circuit in the Woonsocket case that's cited in our brief specifically rejected the proposition that an employer cannot work through his agents in assembling information and be an original source. The whole argument about whether "individual" means not a corporation is based upon the inference that somehow Congress --

THE COURT: I understand that's your argument. I don't even need argument on it because you've both briefed it. I think I'm more interested at this point in the --

MR. BREEN: The relation-back issue.

THE COURT: -- in the relation-back issue, which is just a quirky issue I've always worried about.

MR. DALY: Judge, one thing before I jump to that. The Minnesota Nurses Association case doesn't say what Mr. Breen says it says. That was an association which the court found had no existence apart from its members, and therefore allowed it to proceed because it had no separate legal existence.

THE COURT: It makes no sense for Congress to have drawn this distinction, but it is in fact true they use different terms. In one place they call it a "person," in one place they call it an "individual."

MR. DALY: Right.

THE COURT: You know, it is what it is, but I don't think I need much argument on it.

MR. DALY: No. We'll rest on the briefs on that, Judge.

THE COURT: Yes, I think that makes sense.

So relation back, there is some case law out there, in the First Circuit in particular, that you can cure a subject matter defect and preserve the complaint.

MR. DALY: Judge, I'm not familiar with that --

THE COURT: No, not in whistleblower language.

MR. DALY: Not in this context, right, Judge.

THE COURT: No, in a diversity versus federal question, so --

MR. DALY: Right, you can flip your basis of jurisdiction, but that's a situation where there was always jurisdiction to begin with. What we're saying is --

THE COURT: But it wasn't asserted, I guess.

MR. DALY: Right, but it was there. Here we're saying that when you look at the False Claims Act and you look at Rule 15, it's fairly axiomatic -- and I think we've even cited

some cases where your Honor has said the very same thing -- that you cannot go back to an original complaint and relate back when that complaint has no jurisdiction. There's nothing to relate back to essentially.

THE COURT: You know, what does this new amendment do to that, though, because doesn't that show some Congressional intent to make this as broad as possible? I think when I issued that -- I do agree there's logic to your position. I think it's a difficult intellectual issue. But then I did say that prior to these new amendments, and what do they do to that?

MR. DALY: Judge, I don't think the new amendments do anything. I don't think there's anything in the language of the FERA amendments or in the legislative history that suggest that Congress was creating jurisdiction where none existed. In other words, they certainly didn't abrogate Rule 15, and there's nothing that suggests -- what they're suggesting is that we don't have the problem that -- what was it Baylor? They were taking care of Baylor where we said it's not that the statute -- Baylor held that the statute of limitations --

THE COURT: Yes, I remember Baylor. It was like Chicken Little, the world was falling.

MR. DALY: Right, but it was saying that the statute of limitations wasn't tolled while it is under seal.

THE COURT: I just wish they'd fixed the AWP problem

as quickly as they fixed the Baylor problem, but --

(Laughter.)

THE COURT: That was like within a year the Baylor problem was bailed out, so it's just -- but let me just -- what I find hard is, it's clear Congressional intent is to make this as broad as possible, and it could be viewed that it's essentially expanding the statute of limitations for the government, even if the intervenor doesn't have jurisdiction. It's very difficult. I mean, I know that there's one -- I don't know if any cases have actually flat out ruled on this, have they, on this issue?

MS. OBEREMBT: Well, your Honor, the First Circuit's decision in ConnectU V. Zuckerberg --

THE COURT: That's different.

MS. OBEREMBT: Well, I don't think it is, your Honor, and they directly rely on Justice Scalia's statement in Rockwell where he says nobody has basically questioned the bizarre result that somehow the United States would not be able to pursue its claims in Rockwell because the relator has been dismissed. ConnectU relies directly on Rockwell. They cite it throughout. And, remember, the defendants in ConnectU --

THE COURT: ConnectU wasn't a --

MS. OBEREMBT: It's not a False Claims Act case, but the defendants there are making the identical argument that these defendants are, which is, look, if for some reason

diversity jurisdiction wasn't present when the complaint was first filed, and subsequently there's federal question jurisdiction, somehow you can't relate back to that original complaint for statute of limitations purposes. And the First Circuit said "absolutely not." They used very colorful language involving comparing two different kinds of fruit, if you may recall.

THE COURT: That must have been Judge Selya?

MS. OBEREMBT: Plums and pomegranates I believe he was comparing, two fruits which he believed should not be in the same basket. And he said it's completely different inquiry when you're looking at jurisdiction versus --

THE COURT: But can I narrow you down? I understand you're arguing from there and they're distinguishing that. Am I right that no court in the nation has directly taken this issue head on?

MS. OBEREMBT: You've had one False Claims Act District Court case where it was a declined case where they sought to substitute a relator, and the court said that does not impact jurisdiction.

THE COURT: Was it published?

MS. OBEREMBT: Yes. It's cited in our briefing. We did two very short briefs on this point, your Honor.

And finally FERA, the statutory language is very clear that when the United States intervenes, if its complaints are

based on the same transaction or occurrence, they relate back. And they made that effective to cases pending today.

THE COURT: I understand, but what it doesn't deal with head on, does it relate back to a complaint that is subsequently -- let's even say a trial like Rockwell found to be not the surviving claim or jurisdictional claim? It's an interesting thing that lawyers dream about, but I'm not -- I had ruled to the contrary a while back, but it was pre-FERA, and I have to figure out whether FERA basically extends the statute of limitations regardless of the original -- I may not even be getting there if I think -- right? If Ven-A-Care is an original source, I don't even get to this, is that right?

MS. OBEREMBT: That's correct, your Honor.

THE COURT: But I do need to get to it if even one of the drugs I knock out, right?

MS. OBEREMBT: You do, but, again, I think you've got pretty clear case law on this from the First Circuit.

THE COURT: I don't know that anyone's addressed this head on, and it's a really fabulous law test question, so, again, I will struggle with it.

Now, I think we're done. All right, so let's go off the record for a minute.

(Discussion off the record.)

THE COURT: All right, well, thank you for coming, and thank you for the excellent arguments and briefing. And no

more. Remember, I strike anything that comes in. The only thing I've allowed people to do is to send in supplemental notice of a new case, that's helpful, but no more briefing.

Okay, thank you. See you tomorrow.

THE CLERK: Court is in recess.

(Adjourned, 12:55 p.m.)

C E R T I F I C A T E

UNITED STATES DISTRICT COURT)
DISTRICT OF MASSACHUSETTS) ss.
CITY OF BOSTON)

I, Lee A. Marzilli, Official Federal Court Reporter, do hereby certify that the foregoing transcript, Pages 1 through 133 inclusive, was recorded by me stenographically at the time and place aforesaid in Civil Action Nos. 01-12257-PBS and 06-11337, In Re: Pharmaceutical Industry Average Wholesale Price Litigation, and thereafter by me reduced to typewriting and is a true and accurate record of the proceedings.

In witness whereof I have hereunto set my hand this 8th day of February, 2010.

/s/ Lee A. Marzilli
_____
LEE A. MARZILLI, CRR
OFFICIAL FEDERAL COURT REPORTER